

October 11, 2019

Dear research community,

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

In this issue, you will find:

Important Notifications:

- 1. Tri-Council Policy Statement 2, 2018, TCPS (2018),
- 2. Peak REB submission period,
- 3. Revised consent form,
- 4. New education eModule on Vulnerable Circumstances,
- 5. New REB Reviewer Ethical Merit Assessment Form,
- 6. New IRIS pre-submission checklist,
- 7. Durham College (DC) and Ontario Tech Research Reciprocal Agreement,
- 8. Ongoing recruitment of new REB members.

New Initiatives:

- 9. President's Task Force Quality Improvement Survey
- 10. REB website,
- 11. REB application,
- 12. Pre-approvals for standing practices in research projects,
- 13. Board of Record Research Ethics Review Agreement with Lakeridge Health.

Services available:

- 14. REB consultations,
- 15. Research ethics education.

Important Notifications

 Tri-Council Policy Statement 2, 2018, TCPS (2018) - As of June 2019, Canada's Secretariat on Responsible Conduct of Research released the Tri-Council Policy Statement 2, 2018, TCPS (2018), which replaced TCPS (2014) as the official research ethics policy of the federal research agencies (CIHR, NSERC, SSHRC). Read more about this release at: http://www.pre.ethics.gc.ca/eng/nr-cp_2019-06-05.html.

A summary of the revisions that were published in TCPS (2018) is available in the Highlights of Changes found here: http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_changes.html.

During this transition phase, users are encouraged to continue accessing the current CORE tutorials. The Secretariat is working on developing a new CORE tutorial to incorporate the changes referenced in TCPS (2018). Please stay tuned for the release of the new training modules.

Peak REB submission period - The REB is currently experiencing a high number
of submissions during this time. Peak REB submission periods are from July to
November, which may result in extended review turnaround times. During peak
submission periods, researchers are strongly encouraged to submit their
applications early or, if possible, during non-peak periods to minimize unforeseen
delays.

If you require assistance with your submission or would like to receive a consultation, please feel free to contact the Ethics Office at researchehics@uoit.ca or 905-721-8668 ext. 3693.

3. Revised Consent Form – Revisions to the consent form are complete. The revised consent form serves as a guide to assist researchers to develop a consent form that meets the standards set out by the current guidelines, policies, regulations and research ethics best practices. This template can be tailored to fit the design of your study.

The consent form template is currently available for use on the REB's website under Tips and Samples: https://sites.ontariotechu.ca/reb/index.php

Researchers are strongly encouraged to use the REB's consent form template for future REB submissions.

4. **New education eModule on Vulnerable Circumstances** - Do you experience challenges in understanding and applying 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 Research Ethics Boards (REBs), determine whether the risks and benefits are appropriately balanced in research proposals. Research proposals involving vulnerable populations require greater care and attention as their participation in research may lead to vulnerable circumstances such as inadvertent exploitation and/or long-term consequences.

The Canadian Association of Research Ethics Boards (CAREB-ACCER) created an eModule on vulnerable circumstances that will assist researchers and REB members conceptualize this abstract concept and apply it in real-life research contexts. In particular, this eModule will help research ethics professionals and researchers:

- a. Learn that all human participants are potentially vulnerable either because of the shifting circumstances in which they find themselves in their daily lives or from the risks they may encounter when taking part in research.
- b. Explore how the concept of vulnerability has developed in light of historical events and the key research ethics documents such as the Nuremberg Code and others that were created in their wake.
- c. Explore the tensions 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 "disablism" due to well-meant intentions.

Please contact the Research Ethics Office at researchethics@uoit.ca or 905-721-8668 ext. 3693 for access to the institutional code for this eModule.

5. New REB Reviewer Ethical Merit Assessment Form – The REB reviewer form is available on the REB homepage. REB reviewers use this form to structure and ground the review according to research ethics themes and principles of the TCPS (2018), institutional, provincial and federal regulatory requirements. This form is available to the researchers as a self-assessment tool to complete prior to REB submission to ensure that the application considers the research ethics themes identified on the form to facilitate with the review and approval of the study.

6. **New IRIS pre-submission checklist** – A pre-submission checklist is also available on the REB homepage. The aim of the pre-submission checklist is to ensure that REB applications are complete before submitting in IRIS. This can reduce the time required for the review process.

It is important to note that omissions or incomplete information may result in your application being returned for correction before the application is accepted for review. For this reason, researchers are strongly encouraged to use the presubmission checklist to ensure completeness prior to submission.

7. Durham College (DC) and Ontario Tech Research Reciprocal Agreement – In 2016, Durham College (DC) and Ontario Tech established a framework to coordinate research ethics reviews for joint research and research activities conducted by members at each institution through a reciprocal research ethics review agreement. The agreement established a Board of Record Review (BoR) between DC and Ontario Tech to streamline research ethics review and eliminate the need to submit ethics applications to both institutions. A lead REB (also known as the BoR) would oversee the review and approval of the project, without researchers having to submit to each REB.

In order to qualify for a BoR, the Principal Investigator (PI) must be affiliated with Ontario Tech or DC, or both, and the project must be deemed as minimal risk research. The BoR agreement was renewed for another two-year term.

8. **Ongoing recruitment of new REB members** – The REB members are critical to ensure the success of timely and ethically sound research ethic reviews. For this reason, the REB continually seeks expressions of interest for appointment to the REB for general memberships (3-year term, renewable). Applicants must have knowledge of the TCPS (2018) and current research experience involving human participants.

Interested applicants are asked to email researchethics@uoit.ca a current CV (condensed). Questions about the REB, or the position, can also be emailed to the ethics office at researchethics@uoit.ca or call (905) 721-8668 extension 3693.

New Initiatives

- 9. President's Task Force Quality Improvement Survey In May 2019, the President's REB Task Force sent a quality improvement survey to receive honest feedback from the research community regarding your recent experiences with the REB. A report on the survey responses will follow by the end of this year. Stay tuned for an update.
- 10. REB website Revisions to the REB website are in progress. The new website will feature up to date information about the REB and access to the most recent templates. The current website is accessible in the following link: https://sites.uoit.ca/reb/index.php More information about the launch will follow.
- 11. REB application The REB revised and peer reviewed the REB application. The new REB application includes new questions that are in-line with current standard practices and regulations related to research involving human participants.

The REB is seeking researchers to pilot the new application for future submissions and to provide feedback on the new form. Interested individuals are asked to contact the Research Ethics Office at researchethics@uoit.ca or call (905) 721-8668 extension 3693.

The current REB application is still accessible and available for use in the IRIS research portal.

12. Pre-approvals for standing practices in research projects - For multi-research studies that conduct standard research procedures involving specialized equipment, recruitment of a unique population, and/or standard data collection procedures, a pre-approval application is currently in development that will allow researchers to seek approval for the standard research procedure that can be applied across similar studies.

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 pre-approval application will undergo a review by the REB. Once approved, researchers can append the approved process as an appendix to the REB application. This will eliminate redundancies of answering the same questions in the REB application when the methods were approved in previous applications.

13. Board of Record (BoR) Research Ethics Review Agreement with Lakeridge Health (LH) - Discussions continue with Lakeridge Health (LH) and Ontario Tech regarding a one-way BoR agreement for ethics reviews for research and research activities being conducted solely at LH by Ontario Tech University members. Under the one-way BoR review, Ontario Tech REB will defer the review to LH REB as the BoR, which will eliminate the need to submit REB applications to the Ontario Tech

REB. The aim is to have an executed agreement and Standard Operating Procedures finalized by early 2020.

Services available

14. REB consultations – In person or remote REB consultations are available to all researchers and students for assistance on their REB submission. To name a few, REB consultations are 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; therefore, researchers are encouraged to seek a consultation before submitting an application to the REB.

Please contact the Ethics Office at <u>researchethics@uoit.ca</u> or 905.721.8668 x. 3693 to schedule a consultation.

15. **Research Ethics Education** – Representatives from the REB are available for a presentation or class discussion about research ethics. Please contact the Ethics Office at researchethics@uoit.ca or 905.721.8668 x. 3693 to set up a time.

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 University REB researchehics@uoit.ca