

January 4, 2022

Message from the REB: Research involving in-person human participants under the modified Step 2 provincial plan.

Dear Researchers,

Yesterday, the provincial government announced a return to a modified Step 2 of the Roadmap to Reopen plan effective Wednesday, January 5th, 2022.

In-person face-to-face research will continue under the REB's <u>resumption plan</u> and <u>resumption matrix</u> with modified wording to the informed consent documents. Based on your study status (e.g. previously approved or new submissions), researchers must follow the steps below.

Previously approved in-person face-to-face studies

For all previously approved studies that are actively recruiting and collecting data on human participants, <u>Article 3.3 of The Tri-Council Policy Statement 2</u> regarding re-consent must be applied. Article 3.3 notes, "Consent shall be maintained throughout the research project. **Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.**" The emergence of a new and highly transmissible variant is new information that will impact the study participant's decision to continue with study participation.

Researchers must modify your consent forms through a <u>change request application</u> to include new information about the emergence of a highly more transmissible variant and describe all new attributable risks and benefits related to study participation during a pandemic, if any (TCPS2, Articles 2.10, 3.2c).

Recommended consent wording may include: "At this point in time, the risk of Omicron variant of concern in Ontario is high and the risks of further transmission, severe disease, reinfection, and breakthrough infection in Ontario is moderate with a high degree of uncertainty. The overall risk assessment may change as new evidence emerges (<u>Public Health Ontario</u>, <u>December 2021</u>). We will keep you informed on these changes."

Researchers can submit change request applications through the <u>IRIS Research Portal</u> and must notify the <u>REB Office</u> of your submission. Kindly submit <u>clean</u> and <u>tracked</u> copies of your revised documents and describe your re-consent plan in the change request application.

New in-person face-to-face studies

For all new studies involving human participants, submissions are still accepted through the <u>IRIS</u> <u>Research Portal</u>. Your REB application and consent form must include information found in the:

- REB's Guidance Document on Emerging Ethics Issues Related to Research Conduct During COVID-19,
- REB's COVID-19 consent form clauses found in the REB's <u>Face-to-Face</u>, <u>In-person</u> <u>Consent Form Addendum</u> and recommended consent wording above, and
- <u>TCPS2</u> 's <u>COVID-19 Interpretations</u>.

In addition, evidence of approval from your <u>Faculty On-Campus Research Committee</u> must be included in your submission.

If you have any questions, please feel free to contact the REB at researchethics@ontariotechu.ca. Also, researchers can book consultations with the REB office to facilitate your submission process.

Sincerely,

Dr. Paul Yielder, Interim REB Chair Dr. Ginny Brunton, REB Vice-Chair