

Appendix “J” – University of Windsor Research Ethics Board Research with Human Participants under COVID-19 Restrictions

Under the first version of the *Resumption of Research Framework*, in-person face-to-face research with human participants was suspended until Research Phase 4. This document, *Research with human participants under COVID19 restrictions* outlines the process for researchers who wish to seek an exception to this stipulation and resume, or initiate, research with human participants that includes in-person, face-to-face data collection with planned, controlled and time-limited breach of physical distancing during Research Phase 2 or Phase 3.

The University of Windsor REB is accepting and reviewing all new application submissions and will *conditionally clear* applications even if the research cannot be conducted at this time due to COVID-19 restrictions. This continuance of review is to prevent a backlog of submissions once COVID-19 restrictions are removed. Timelines may be longer than normal given the volume of applications and remote working environment. Please contact the Office of Research Ethics with any questions or concerns: ethics@uwindsor.ca.

Considerations

Guidelines from the Panel on Research Ethics

Researchers are encouraged to consult the interpretations by the Panel on Research Ethics in applying the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS 2 (2018)* during the current COVID-19 public emergency. The link to the interpretation can be found here: https://ethics.gc.ca/eng/nr-cp_2020-09-02.html

On-campus research

Research that brings human participants onto campus to engage in data collection procedures, whether students or community members, must follow all safety protocols required of individuals coming onto campus. For the requirements for coming onto campus, please see: <https://www.uwindsor.ca/returntocampus/336/before-going-to-campus>. All research participants coming onto campus to engage in research projects must complete the Safe Lancer App or screening form and forward this information to the researcher prior to coming onto campus. Please see the REB COVID19 Consent Amendment for procedures.

Field research

Research to be conducted off-campus with human participants must follow all health and safety guidelines required by the location in which the research is taking place. The researchers must obtain RSC approval for the health and safety measures and provide the REB with the information listed below.

Students

Students who are approved to be on campus as research assistants, attending courses, or other reasons, cannot be assumed to be recruited as research participants. Researchers who

intend to recruit students for in-person face-to-face studies must ensure that recruitment and consent procedures reinforce voluntary participation and are free from undue influence. This may require modifications to recruitment procedures such as using a someone not involved in the research to assist with recruitment. The REB reminds instructors that they may not recruit students in their courses for their research unless previously cleared by the REB. Faculty researchers must also reinforce that their participation is voluntary and is free from undue influence.

Vulnerable Populations

Research that involves visiting or breaching physical distancing requirements with vulnerable populations or communities *will not resume at this time*. Please note that all virtual/on-line research can continue if there is no direct in-person face-to-face contact with participants.

Vaccination Status

Researchers may wish to use vaccination status as a criteria for participation in research that includes breaches of physical distancing. While considering vaccination status may assist in meeting the principle of Concern for Welfare by addressing the risks to individual participants, it may also limit fair and equitable selection of participants under the Justice Principle by preventing some groups from participating in research and limiting research results to only vaccinated populations. Researchers should decide what is most appropriate for their specific research projects. If researchers do decide to use vaccination status as inclusion/exclusion criteria, this should be made known to potential participants during recruitment and included in the consent process. The new “Consent Addendum for COVID-19 Risks and Procedures for In-Person Research at the University of Windsor” includes an optional question on vaccine status.

Process for applying for an Exception for in-person face-to-face research with planned, controlled and time-limited breach of physical distancing research with human participants

Exceptions for *previously REB-cleared* research

Researchers wanting to resume face-to-face in-person data collection under a previously REB- cleared application must submit a Request to Revise (<https://www.uwindsor.ca/research-ethics-board/298/forms>) to the REB that includes the following information:

- 1) Research Safety Committee (RSC) documentation of their approval of the health and safety measures and necessary PPE for the conduct of the research.
- 2) Description of modifications to the research protocol--specifically:
 - a. Information provided to participants on complying with campus requirements to arrive and depart from the research site;
 - b. Modification of procedures to comply with health and safety expectations of RSC;
 - c. **NEW Include the ‘Consent Addendum for COVID-19 Risks and Procedures for In-Person Research at the University of Windsor’**

Exceptions for *new research* submissions

New REB application submissions which include in-person procedures which will breach physical distancing requirements will be conditionally cleared awaiting RSC approval. Researchers submitting applications that include in-person face-to-face data collection who are not sure if they will seek an exception, may submit their application to the REB for conditional clearance. Should the researchers decide later to seek an exception, they may follow the instructions under Exceptions for previously REB-cleared research.

Step One: Dean's approval.

Resumption of Research Phase 2 or 3 Form whichever is applicable and **approved** by the Faculty Dean/Department Head.

Step Two: Research Safety Committee (RSC) approval.

Obtain approval from RSC Committee for the health and safety measures and necessary PPE for the conduct of the research.

Step Three: REB clearance.

Submit the following to the REB:

1. Request to Revise form or New Application Form
2. Research Safety Committee (RSC) approval
3. Description of modifications to the research protocol--specifically:
 - Information provided to participants on complying with campus requirements to arrive and depart from the research site;
 - Modification of procedures to comply with health and safety expectations of RSC;
 - **NEW Include the "Consent Addendum for COVID-19 Risks and Procedures for In-Person Research at the University of Windsor"**

Final Step: VPRI Approval.

Please note that the Vice-President, Research and Innovation (VPRI) has the final approval for all research resumption and the VPRI's authorization must be sought upon receiving REB clearance.