

University of Windsor Research Ethics Board **Research with human participants under COVID19 restrictions**

On June 1, 2020 the University of Windsor implemented *The Resumption of Research Framework* to guide a phased approach to resuming research:

https://www.uwindsor.ca/vp-research/sites/uwindsor.ca/vp-research/files/uwindsor_framework_for_resumption_of_research_may_29_2020_final.pdf

Under the ***Resumption of Research Framework***, in-person face-to-face research with human participants is 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.

Reminder:

- Research conducted with human participants that does not require in-person face-to-face data collection and can be conducted virtually/on-line, **MAY CONTINUE** and is **NOT** suspended. Researchers are encouraged to conduct research virtually/on-line to the fullest extent possible.
- The University of Windsor REB is accepting and reviewing all new application submissions and will *conditionally clear* applications even if the research is not intended to be undertaken 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.

Requesting an exception to the *Resumption of Research Framework* stipulation that face-to-face research can only be resumed in Research Phase IV

If you wish to resume previous research or conduct new research that involves in-person face-to-face research with planned, controlled and time-limited breach of physical distancing – please note the following:

Research Phase 2: Research that is *COVID-19 related, time-sensitive and essential* requiring in-person face-to-face and planned, controlled and time limited breach of physical distancing can be approved as an exception to the guidelines in the *Resumption of Research Framework*.

Research Phase 3: Research that is COVID-19 or Non-COVID-19 research with human participants that cannot be conducted virtually/on-line and requires in-person, face-to-face and planned, controlled and time-limited breach of physical distancing data collection can be considered for an exception to the guidelines under *The Resumption of Research Framework* on a case-by-case basis.

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>

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 someone not involved in the research or a third party to assist with recruitment. The REB reminds instructors that they may not recruit students in their courses for their research projects unless previously cleared by the REB. Furthermore, in addition to the mandatory “Risk Acknowledgement Form” required of student research team members within the Framework, faculty researchers must also reinforce that their participation is voluntary and is free from undue influence.

Vulnerable Populations

Research that involves visiting or direct contact 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.

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) Resumption of Research Phase 2 or 3 Form (<https://www.uwindsor.ca/vp-research/353/covid-19-research-and-innovation-guidance>) whichever is applicable and approved by the Faculty Dean/Department Head.
- 2) Research Safety Committee (RSC) application and documentation of their approval of the health and safety measures and necessary PPE for the conduct of the research. 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 conditional clearance—see note below.
- 3) 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. Modifications to the consent process and confidentiality based on record-keeping or contact tracing information;
 - d. Other modifications that may be necessary to address issues related to COVID-19 situation.
- 4) Description of revised risks and mitigation strategies including RSC health and safety requirements and necessary PPE.
- 5) Modifications to the consent process and form which include any revised procedures, risks and protection for the participant, and any other information necessary for an individual to make an informed choice regarding participation in the research study.
- 6) List the location, and *anticipated* days and times for data collection. Please update the REB and RSC as dates and times are confirmed and revised as the study progresses. This is to assist the researcher should any questions arise on REB clearance or compliance with RSC approved health and safety procedures.

Upon receiving the above information, the REB will review and provide conditional ethics clearance. Researchers must then seek final authorization from the VPRI for the exception.

Exceptions for *new research* submissions

New REB application submissions in which the Principal Investigator intends to submit a Request for an Exception to conduct research that includes in-person face-to-face data collection with planned, controlled and time-limited breach of physical distancing, must include the information listed above in items 1-6 with the new application. **The REB will provide**

conditional clearance; final authorization for any new research requiring an exception must be sought and issued by the VPRI as noted above.

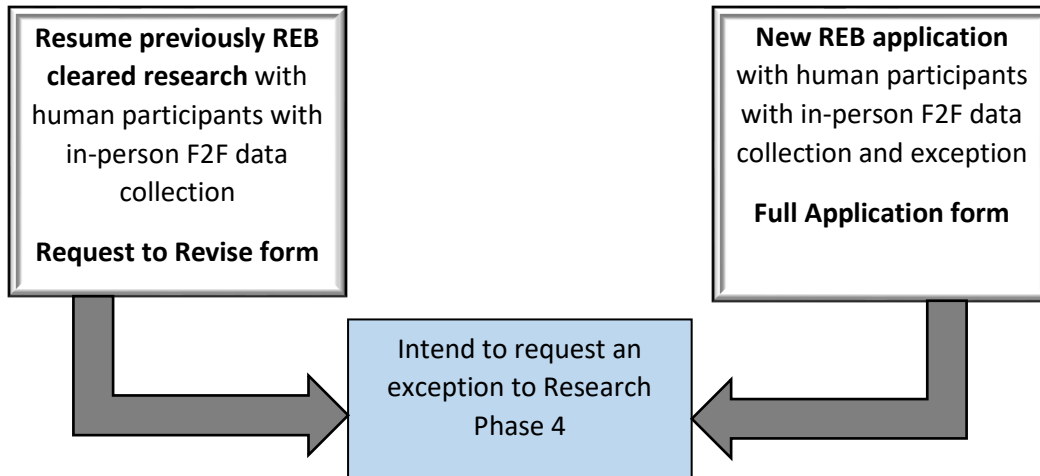
Researchers submitting applications that include in-person face-to-face data collection who are not sure if they will seek an exception, may submit their application to the REB for conditional clearance. Should the researchers decide later to seek an exception, they may follow the instructions under Exceptions for previously REB-cleared research.

Timelines for review

Timelines may be longer than normal given the volume of applications and remote working environment. The REB is prioritizing COVID-19 related research and Requests to Revise to modify procedures to collect data virtually/on-line.

The REB continues to review research applications assessed as minimal risk through the Delegated Review Committee which meets weekly. Applications assessed as having greater than minimal risk are reviewed monthly at the Full Board level and biomedical applications are reviewed monthly by the Biomedical Board. COVID-19 related research undergoes rapid review by select members from the Full Board or through a subcommittee of the Biomedical Board. Administrative research, secondary use of data, requests to revise, and all other queries continue to be reviewed daily at the Executive level.

Framework for the Resumption of Human Research



Step One: Dean’s approval.
 Resumption of Research Phase 2 or 3 Form (<https://www.uwindsor.ca/vp-research/353/covid-19-research-and-innovation-guidance>) whichever is applicable and **approved** by the Faculty Dean/Department Head.

Step Two: Research Safety Committee (RSC) approval.
 Application and documentation of their approval of the health and safety measures and necessary PPE for the conduct of the research.

Step Three: REB clearance Submit to REB:
 1. Dean’s approval
 2. RSC’s application and approval
 3. **Request to Revise form** for resumption of previously cleared REB application –or-- **Full Application form** for new research
 4. Description of modifications to the research protocol for COVID19-- specifically:
 a. Information provided to participants on complying to arrive and depart from the research site;
 b. Modification of procedures to comply with health and safety expectations of RSC;
 c. Modifications to the consent process and confidentiality based on record-keeping or contact tracing information;
 d. Other modifications that may be necessary to address issues related to COVID-19 situation.

4) Description of revised risks and mitigation strategies including RSC health and safety requirements and necessary PPE.

5) Modifications to the consent process and form which include any revised procedures, risks and protection for the participant, and any other information necessary for an individual to make an informed choice regarding participation in the research study.

6) List the location, and *anticipated* days and times for data collection. Please update the REB and RSC as dates and times are confirmed and revised as the

Final Step: 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 conditional clearance.