

**COVID-19 Update: Considerations for New Initial REB Applications
and Amendments for ongoing studies**

Highlights

- Any new or resumed on-campus, community-based or field research must first be approved by your Dean, designated Department Chair, School Director or Chair/Chiefs.
- Protocol changes no longer considered urgent or temporary to eliminate risks must now be submitted as amendments, including those initially submitted as FYIs.
- General modifications due to public safety guidelines do not require amendments.

Dear Colleagues,

Given persisting public health recommendations to maintain social distancing and to adhere to other related safety precautions, Western University's research ethics boards (REBs) encourage all researchers to exercise sound judgment and to speak to their Deans/Department Chairs or Chair/Chiefs and the REB when considering their research programs and specific ethics protocols.

On May 29, the Vice-President (Research) distributed a [COVID-19 Research Recovery Plan](#) that outlines Western's four-phased plan for returning to campus. If you are considering restarting or initiating any on-campus, community-based or field research, you must first receive approval from your Dean or designated Department Chair or School Director (Western) or your Chair/Chiefs (Lawson).

During the early phases of the pandemic, the Office of Human Research Ethics updated its processes to address immediate and temporary changes needed to eliminate risks to participants using the FYI notification feature in WREM.

Changes no longer considered urgent or temporary to minimize participant risk must now be submitted as amendments for REB approval, including those initially submitted as FYI.

When considering submitting an amendment:

- General modifications due to public safety guidelines **do not** require an amendment (e.g., standing two metres apart, wearing masks, etc.);
- Changes to study procedures as a result of public safety guidelines **will** require an amendment (e.g., switching from an in-person focus group to individual interviews or online data collection);
- Any additions of COVID-related inquiries to an existing study (e.g., additional questions/analyses) must be related to the original research questions/objectives; otherwise, please submit as a new REB application;

Modified study procedures may be carried out with REB approval when feasible, and only when appropriate. There may be instances when it is not appropriate to make a specific change (e.g., conducting in-person interviews about a sensitive topic and with a vulnerable population may not be appropriate to switch to online interviews; therefore, study activities may still have to be on hold until social distancing requirements are not required). Different considerations will be needed depending on

the type of research and typical procedures for that study team. The logistics for any prospective research must be carefully considered.

Below are some considerations to evaluate prior to submitting an REB application.

General

- Is it necessary to conduct this research immediately?
- Can my research question be adequately answered using a modified (e.g., remote) design?
- Is it feasible to adapt my research for remote facilitation?
- Consider providing options in the application for face-to-face AND remote options as needed. Be proactive in considering options to avoid further amendments.
- For new Initial Applications: if you are conducting COVID-specific research, ensure you include “COVID” in the full study title of the REB application.

Considerations when modifying study procedures

- Any specific needs among your population
- Privacy, confidentiality and data security
 - When conducting research remotely (i.e., outside of institutional firewalls and/or physical security protections), researchers must take additional caution to protect participants' privacy, confidentiality, and data security (also ensuring to follow institutional policy).
- Recruitment and informed consent procedures
- Data quality and academic scrutiny
- Institutional requirements
- Public health and safety guidelines

Modifications to Consent

- Verbal: A script and method of documentation is required for review.
- Electronic (Lawson REDCap, email). NOTE: you will need to consider and describe how you will verify participants' identities in your application to the REB.
- Implied (i.e., completion of survey (e.g., Western Qualtrics))

*Appropriateness depends on the study design, participant characteristics, risks, etc.

*Prior to submitting an initial application or amendment, please think through the logistics of obtaining, storing, and documenting **informed** consent.

Privacy, Confidentiality and Data Security

- Become familiar with all features of your selected online platform and ensure to set up your project/data collection in a way that mitigates any privacy, confidentiality or data security risks.
- Ensure any technological platforms being used have been vetted by the institution.
- Be specific in the REB application by explaining any technical measures for protecting participants.



- Consider creating a guide/tool/resource outlining mechanisms in place to minimize risks and/or participant burdens.
- NOTE: Email is not a secure method of communication. Caution should be exercised when using email for research purposes. Participants must be informed of the limitations to confidentiality when using email, and their prior consent obtained for such communications.

Common Online Tools:

- Western's Zoom
- Western's OWL or Blackboard Collaborate
- Western's Office 365 Suite (incl. OneDrive)
- Western's Qualtrics
- Lawson's REDCap
- Lawson's WebEx

Others may be appropriate depending on researchers' needs, but institutional review (i.e., Western's Technology Risk Assessment Committee, Hospital's Authorized Technology) may be required.

Contact your institutional IT personnel for more information and/or technical support.

Additional Resources

- ["Ask an Ethics Officer" Presentation](#) (May 28, 2020)
- [Office of Human Research Ethics Communications](#)
- [Office of Human Research Ethics – Resources and Presentation Material](#)
- [Western Research COVID-19 Updates](#)
- Western University [Research Recovery Plan](#)
- Western University [Research COVID-19 FAQ](#)
- Lawson [COVID-19 Updates](#)

If you have any questions/concerns please contact the office at ethics@uwo.ca or 519-661- 3036.

Sincerely,

A handwritten signature in black ink, appearing to read "Erika Basile".

Ms. Erika Basile,
Director, Research Ethics and Compliance, Western University