Western Research

VIRTUAL CONFERENCE • SPRING 2020

ASK AN ETHICS OFFICER

Office of Human Research Ethics

Overview

- Important Notes
- Institutional Updates
- OHRE Administrative Notes
- Protocol Considerations During COVID
- Meet the OHRE Team
- Q&A Session

Important Notes

- This session is being video-recorded.
  - The video-recording and accompanying will be made available to the Western research community through the registration page.

- Due to the number of attendees, we kindly ask that you:
  - Keep your video function turned off;
  - Keep your microphone muted; and
  - Please use the Chat function to ask your questions throughout the session. They will be answered in the Q&A session.

Important Notes

- Thank you for sharing your questions in advance!
- FAQ handouts will be provided after the session. Please stay tuned.
- You will be contacted after the session to participate in a short survey. We look forward to your feedback.

Office of Human Research Ethics

- Reminders:
  - OHRE facilitates the review and approval research in accordance with federal, provincial and institutional regulations, guidelines, legislation and policies associated with the ethical conduct of **research**.
  - Ethical considerations regarding research are separate from (and in addition to) institutional and governmental (e.g., public health, legal, etc.) directives.
  - Even if Research Ethics Board (REB) approval is received, researchers must ensure they have the appropriate institutional permissions to conduct their research.

Institutional Updates

Timelines, safety protocols, and liability regarding lab-based, clinical, and/or field research are institutionally determined.

WESTERN:

- Refer to
  - https://www.uwo.ca/research/research_western_covid19_updates.html
  - https://www.uwo.ca/research/recovery-plan/
- Consult with Unit directors/Deans for approval.

LAWSON:

- Refer to
  - https://www.lawsonresearch.ca/coronavirus-covid-19-updates
- Consult with Chair/Chiefs for approval.

OHRE Administrative Updates

- Business ‘as usual’ (just remotely)
  - Some research has been unaffected by COVID.
  - Other applications are reviewed and approved with the understanding researchers will obtain institutional approval prior to commencing their research.

- Our timelines are expected to remain steady, with a priority on COVID-specific investigations.

OHRE Administrative Updates

- Update to Memo released March 13, 2020 re: FYIs:
  - This mechanism was intended to facilitate **immediate** and **temporary** logistical changes to eliminate risk in response to the early stages of the pandemic.
  - Changes that are no longer urgent or temporary should be submitted as amendments for REB approval.

- If you are adding a COVID-related inquiry to an existing study (e.g., additional questions/analyses):
  - These must be related to the original research questions/objectives, and an amendment for REB approval is needed.
  - Otherwise, submit as a new REB application.

OHRE Administrative Updates

- If you are conducting COVID-specific research:
  - Please include “COVID” in the Full Study Title of the REB application (for reporting purposes).
  - If hospital-based studies, institutional ***pre-review*** is required (see Lawson intranet for more details).

**Remember to consider all logistics of your study and ensure applicable ethical, institutional, and administrative considerations are addressed in the initial REB application.*

OHRE Administrative Updates

- Notes re: Amendments:
  - Generalized modifications due to public safety guidelines do not require an amendment.
  - Changes to study procedures as a result of public safety guidelines will require an amendment.

- Example:
  - Standing 2m apart, wearing masks, etc. does not need to be submitted as an amendment.
  - Switching from an in-person focus group to individual interviews OR online data collection does require an amendment.

Considerations for New and Amended Research

- Is your research **essential**?
  - *Consult with PI/Chair/Chief/Unit Head/Dean.*

- Is your research **time sensitive**?
  - *Consider degree requirements, funding deadlines, etc.*

Due to the uncertainties and inevitable restrictions that will be placed on research for the foreseeable future, researchers and scholars (including students) need to make mindful and difficult decisions regarding their work.*

REB Considerations for COVID-Related Protocol Modifications

- Can your research question be adequately answered following modified study procedures?
  - *Note: Changes to methodology may be needed.*

- If it is feasible to adapt your research to be conducted remotely, what modified study procedures might be appropriate to answer your research question?

- Consider providing options in the application for face-to-face AND remote options as needed. Be proactive in considering options in order to avoid amendments.

REB Considerations for COVID-Related Protocol Modifications

NOTE:

These suggestions are ONLY appropriate WHEN appropriate…

Discretion must be exercised!

Revised procedures must be justified, all logistics considered, and REB approval obtained.

REB Considerations for COVID-Related Protocol Modifications

- At a high level, think about:
  - Any specific needs among your population
  - Privacy, confidentiality, and data security
  - Recruitment and informed consent procedures
  - Data quality and academic scrutiny
  - Institutional requirements
  - Public health and safety guidelines

REB Considerations for COVID-Related Protocol Modifications

- The REB evaluates research from the perspective of the participant experience and associated risks/harms *as a direct result of the research.*
  - Researchers are responsible for adequately addressing these risks and informing participants of any applicable information.
  - The REB is not in a position to advise regarding PPE or other safety measures.
- BUT, any precautions employed by the researcher *that affect the participant experience* do need to be communicated to participants as part of the informed consent process.
  - The REB will review and approve these communications, but the REB will not determine appropriateness of such protocols.

REB Considerations for Remote Study Designs

- Potential Online Data Collection Options:
  - 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 privacy) may be needed.

REB Considerations for Remote Study Designs

- Modified consent procedures:
  - Verbal – *A script and method of documentation is required for review.*
  - Electronic (Lawson REDCap, Western's Qualtrics, email)
  - Implied

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

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

Communication of applicable info (REB application)

- TIPS:
  - Ensure any technological platforms being used have been vetted by the institution.
  - Be specific in the REB application explaining any technical measures in place to protect participants.
  - Consider creating a guide/tool/resource outlining mechanisms in place to minimize risks and/or participant burdens.

  Examples:
  - Password-protected video-conferencing links, asking participants to remove any identifiable information, etc.

Communication of applicable info (LOI/C)

- TIPS:
  - Specify the online tool being used to facilitate the research.
  - Outline the logistical steps participants need to know.
  - Anticipate and minimize participant burden as much as possible.
  - Describe the confidentiality limitations due to third-party platforms.
  - Indicate who will have access to information, for how long, and for what purpose.
  - Outline the measures in place to mitigate any privacy, confidentiality, and/or data security risks.

Office of Human Research Ethics

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Q&A

- Please enter your questions and/or comments in the Chat box.
- Questions will be triaged and answered one at a time by the OHRE team.
- If your question has not been answered, please follow up with us directly!

Q&A - Submitted

- Review Timelines
- Multijurisdictional Research
- PI eligibility
- Answering WREM Questions
- Master Lists
- Need more detail ***Expect contact from an EO***

Thank you!

Stay tuned for the handouts and survey via email.

The recording and slides will be available at: https://www.uwo.ca/research/about/rw_conf.html

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