



Western
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Human Research Ethics Workshop

Faculty of Education

Katelyn Harris

katelyn.harris@uwo.ca

Research Ethics Officer

November 20, 2023

Disclaimer

The information provided in this presentation is consistent with the current policies and guidelines laid out within the Office of Human Research Ethics (OHRE), Western University's Research Ethics Boards (REBs), the University, and the Tri-Council Policy Statement (TCPS2, **2022**), which are *subject to change*.

Overview

- Recap of research ethics principles/ REB process
- Highlight of resources
- Emerging topics/updates
- **Q&A**

TCPS2 Core Ethical Principles

- **Respect for persons** - Right to choose; autonomy; free, informed and ongoing consent
- **Concern for welfare** (or *beneficence* according to other policies) - Obligation to do good; benefits outweigh risks
- **Justice** - Fairness and equity; justifiable inclusion; balanced power relationships

Apply to research even when REB review is not needed

Does all Human Participant Research Require REB Review?

Projects relying on the following data sources **may** be exempt from REB review:

- **publicly** available information (*see TCPS2 Article 2.2*)
- **naturalistic** observation (*see TCPS2 Article 2.3*)
- secondary use of **anonymous** information (*see TCPS2 Article 2.4*)

Activities involving humans that do not meet the TCPS2 definition of research may also be exempt:

- quality assurance/quality improvement/program evaluation (*see TCPS2 Article 2.5*)
- creative practice (*see TCPS2 Article 2.6*)


When in doubt, assume REB review is needed, and...

- Consult the **TCPS2** (*note: human ethics training is mandatory for any study team members conducting human participant research*)
- Visit the Human Research Ethics **website** for more information:
 - <https://www.uwo.ca/research/ethics/human/index.html>
 - <https://uwo.ca/research/ethics/human/workshops/index.html>
- Contact the **OHRE** (ethics@uwo.ca) for discussion.

Always exercise due diligence **before starting research that may involve humans or their data**

Human Research Ethics at Western

Research Ethics Applications Help ▾ Log in

 **Western Research**

Ethics Manager (WREM) - most recent update: September 10 & 11, 2019 - Please clear your browser history and cache to mitigate any issues with the latest update.

Log in

Email Address

Password

[Log in](#) [New User](#) [Forgotten Password](#)

HELP Tab: FAQs;
WREM online
videos, tutorials,
REB templates/
guidance
documents;
OHRE contact info.

New users must register here for an account, which will be issued in approx. 1 business day.

WREM Application Forms

Initial HSREB or **NMREB** Form

This is the main application form to be used for all projects requiring Research Ethics Board (REB) review.

Multijurisdictional Form

This form is used to help Western researchers determine if Western's REB oversight is required for their role in collaborative, multi-jurisdictional research projects. See Multijurisdictional guidance document.

QA/QI/PE Form

To confirm whether a project is considered Quality Assurance (QA), Quality Improvement (QI) or Program Evaluation (PE), and therefore does not require REB oversight, submit this form. See QA/QI/PE guidance document to help you determine if your project is research or not.

Pedagogical Form

Pedagogical research projects being carried out within the context of a course require the instructor to submit this form. See Student Research and Pedagogical Activities guidance document for more information.

Cadaveric sub-REB Form

All research involving human biological material obtained through Western's body bequeathal program must be submitted through this form.

Human Research Ethics at Western

<https://uwo.ca/research/ethics/human/deadlines.html>

Health Science Research Ethics Board (HSREB)

Research that takes place inside a medical or health care environment or that involves medical patients or medical patient data

Full Board Review

Prospective research > minimal risk

Delegated Level 1 (DL1) Review

Retrospective Research =/< minimal risk

Delegated Level 2 (DL2) Review

Prospective research =/< minimal risk

Non-Medical Research Ethics Board (NMREB)

Includes social, behavioral and cultural research in a non-clinical, non-patient-based population

Full Board Review

Research > minimal risk


Delegated Review

Research =/< minimal risk

Minimal Risk: potential harms are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Approval

Do **NOT** start any research activities until you have received an REB Approval Notice (sent via wremsend).

 Western Research	Research Ethics	
Western University Health Science Research Ethics Board HSREB Full Board Initial Approval Notice		
Principal Investigator: Department & Institution: Schulich School of Medicine and Dentistry/Oncology, London Health Sciences Centre		
HSREB File Number: Study Title:		
Sponsor:		
HSREB Initial Approval Date: January 20, 2015 HSREB Expiry Date: January 20, 2016		
Documents Approved and/or Received for Information:		
Document Name	Comments	Version Date
Instruments		
Wallet Card		
Instruments		

Required Post-Approval Submissions (i.e., Action: “Create Sub-Form” in WREM)

Amendment

- Modifications to the approved application and/or study documents.
- Amendments must be approved prior to implementation.

Reportable Events

- **Protocol Violation/Deviation** = unapproved study activities
- **Serious Adverse Event** = harmful outcome to study participant
- **FYI** = minor updates to REB
- **Data Safety Monitoring Board/Committee (DSMB/C) reports**
- **Participant complaints/privacy breaches*** contact REB prior to submitting reportable event in WREM

Continuing Ethics Review (CER)

- Annual update required for studies extending beyond one year.
- Receipt of CER approval notice required for study continuation.

Study Closure

- End of study report required when there is no further participant involvement, and all data collection, clarification and transfer is complete (including access to participants’ medical record).

Multi-Jurisdictional Research, Indigenous Research, Qualitative Research

**See TCPS2 Chapters 8, 9 and 10*

- Regional and institutional differences; researchers must adhere to all applicable requirements.
- Ensure appropriate community engagement prior to, during, and after the research is conducted.
- When conflicts arise between regional/institutional/disciplinary expectations and/or cultural norms, discuss with the REB(s).
- Amendments may be appropriate due to the emergent nature of some studies.

Conducting Research in Schools

- Research involving K-12 education system:
 - School/Board approval required.
 - Prepare for submission deadlines.
 - Will any information be collected from the school/school board (e.g., IEP, report cards, etc.)?
 - Will any information be reported back to the school/school board?

Conducting Research in Schools

- Research involving K-12 education system:
 - Consider logistics:
 - In-school activities (incl. when/where? background checks?)
 - Recruitment/consent (incl. parent/guardian consent/student assent)
 - Confidentiality and voluntary participation (incl. limitations)

Conducting Research in Schools

- Research involving K-12 education system:
 - Consider vulnerability/risk:
 - Students are ‘captive audience’
 - Parents receive large volumes of permission forms
 - Age of students: age-appropriate communications about the research
 - Waivers of parental consent (sensitive topics)

Always evaluated on a case-by-case basis

Conducting Research in Schools

- Research involving postsecondary education system:
 - **Within your own classroom?** *Contact CTL for recent presentation materials*
 - **At Western?** *See REB Participant Recruitment Guidelines*
 - **At other Canadian institutions?** *Consult their REBs for review requirements*
 - **Outside of Canada?** *Confirm local requirements.*

Key Details in the REB Application

- Study team members
- Research objectives/procedures/instruments
- Participant characteristics (inclusion/exclusion)
- Risks/benefits
- Recruitment strategy*
- Informed consent procedures*
- Privacy, confidentiality, data security*

*Use Western's REB guidelines and templates:

https://www.uwo.ca/research/ethics/human/board_guidelines.html

EDI Considerations

- Development of research questions/design
 - How did you come to develop your questions?
 - Who/what informed the need for the research?
 - Whose voices will be included?
 - Who will be involved in (co)analyzing the data?
 - How will attributions be navigated, balancing privacy/confidentiality?

EDI Considerations

- Collection of demographics:
 - Must be **justified**, grounded in the literature
 - Participants must be **informed** and consent to the collection of this information for the stated purposes
 - Participants' **privacy/confidentiality** must be prioritized (e.g., limitations due to small sample or combination of indirect identifiers?)
 - Researchers are responsible for ensuring groups/communities are **appropriately represented**

Emerging Issues

- Secondary Use of Research Data
 - Originally collected for research purposes; now proposed for a **new purpose**
 - Did the participants consent to the future use of their data? See **TCPS2 Article 3.13**
(https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#e)
 - See also **TCPS2 Article 5.5A/B**
(https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html)

Emerging Issues

- Use of Social Media in Research
 - Complex context
 - May or may not require REB oversight
 - See TCPS2 Guidance Document: ***Does Research Using Social Media Platforms Require Research Ethics Board Review?*** (https://ethics.gc.ca/eng/reb-cer_social-sociaux.html)

Emerging Issues

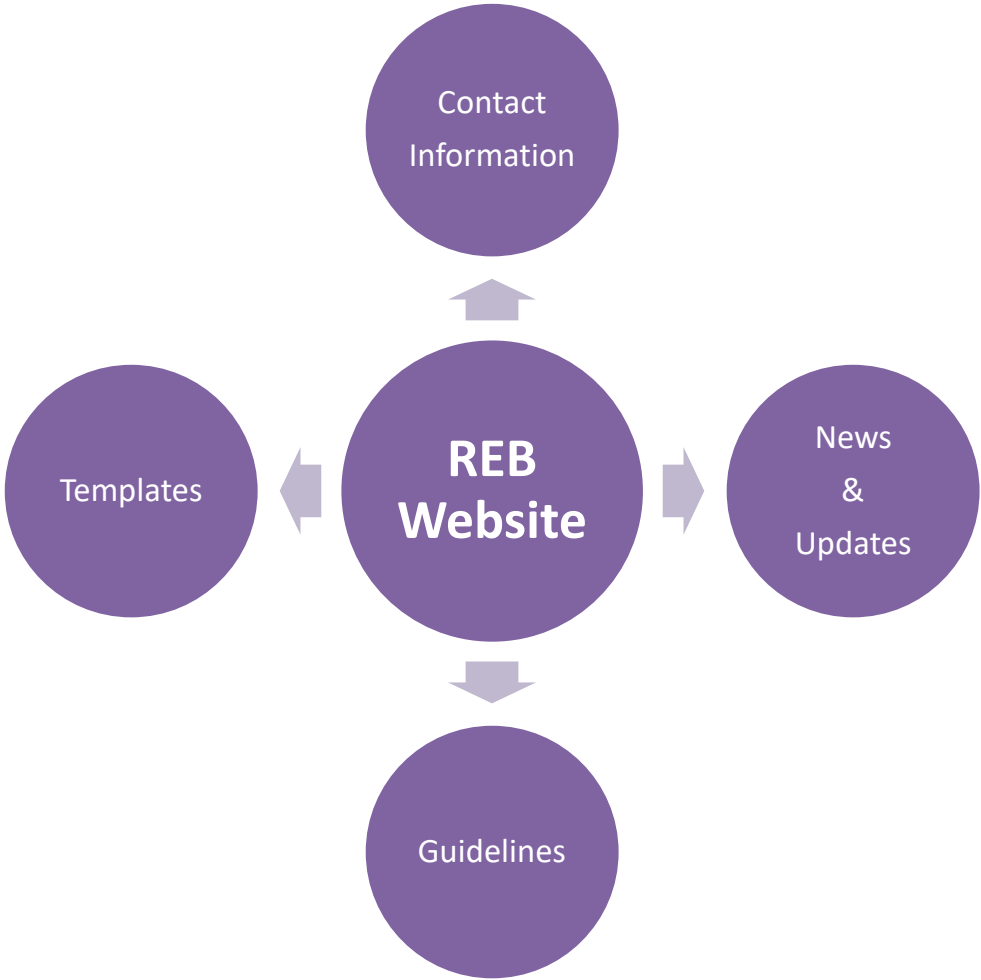
- Use of AI in Research
 - Any intentions to use AI in research requiring REB review should be disclosed in the REB application

OHRE staff are currently seeking out:

- *Educational opportunities*
- *Someone with this area of expertise to join the Board*

In sum...

- There is a lot to consider!
- Get started early and think through the logistics of your project.
- Become familiarized with the WREM system and REB guidance and templates.
- Reach out! We're here to help.



Thank you!



QUESTIONS?
OPEN DISCUSSION?



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