Research Ethics Considerations: REB Review at Western University

Faculty of Education

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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, 2018), which are subject to change.
Overview

- **Introduction** to research ethics requirements
- **Submitting REB applications** at Western University
- Key **tips and tricks** for successfully and promptly receiving REB approval
- **Special considerations** within the faculty of education
- **Q&A**
Legal, Ethical and Institutional Considerations

• Privacy Legislation (e.g., FIPPA, PIPEDA, PHIPA)

• Tri-Council Policy Statement 2 (2018); Health Canada; OCAP; ICH-GCP

• Western University:
  – MAPP 1.13, MAPP 1.23, MAPP 7.0, MAPP 7.14
  – Western Technology Services’ Information Governance, Data Classification, and Data Handling Standards
  – REB Data Security and Confidentiality Guidance Document

• Lawson Health Research Institute’s Standard Operating Procedures
REB Exemptions (see TCPS2 Chapter 2)

The following examples **MAY** be exempt from REB review:

- Research relying on publicly available information
- Research on organizations, not involving personal data/opinions
- Secondary use of _anonymous_ information
- Naturalistic observation of people in public places
- Quality Assurance/Quality Improvement/Program Evaluation (QA/QI/PE)
- Creative practices
Research Ethics Oversight at Western

- Office of Human Research Ethics (OHRE) – Administrative unit facilitating REB operations.
- Non-Medical Research Ethics Board (NMREB) & Health Sciences Research Ethics Board (HSREB)

**Location:** Support Services Building, 5th Floor (Rm 5150)

**Phone:** 519.661.3036

**Email:** ethics@uwo.ca

**Website:**
https://www.uwo.ca/research/ethics/human/index.html

**Virtual Office Hours:** Wed mornings; sign up on OWL (see Contact Us webpage)
# Our Staff

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Western’s REB Review Procedures

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

HELP Tab: FAQs; WREM online videos, tutorials, REB templates/guidance documents; OHRE contact info.
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.
# Western’s REB Review Procedures

## 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

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<th>Risk Level</th>
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<tr>
<td>Full Board Review</td>
<td>Prospective research &gt; minimal risk</td>
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<tr>
<td>Delegated Level 1 (DL1) Review</td>
<td>Retrospective Research =/&lt; minimal risk</td>
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<tr>
<td>Delegated Level 2 (DL2) Review</td>
<td>Prospective research =/&lt; minimal risk</td>
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## Non-Medical Research Ethics Board (NMREB)
Includes social, behavioral and cultural research in a non-clinical, non-patient-based population

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<tr>
<td>Full Board Review</td>
<td>Research &gt; minimal risk</td>
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<tr>
<td>Delegated Review</td>
<td>Research =/&lt; minimal risk</td>
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**Minimal Risk:** potential harms are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Western’s REB Review Procedures

**Initial Reviews**

New studies that have not yet been approved by an REB, and have not yet started.

**Post Approval Events**

Changes or updates to an REB submission that has previously received approval and may already be underway.

Note: Applications must be submitted by the PI.
Western’s REB Review Procedures

Who can be PI? Only those who are eligible to hold a research account:

• Individuals are deemed eligible based on their job requirements; typically research-eligible faculty members.
  • IMPORTANT NOTE: Students/postdocs cannot be PI.
• Those with responsibility to conduct independent research with the support of their chair and/or dean.
• Refer to document: Eligibility to Hold a Research Account at of Western University
• Questions? Speak to your Chair/Dean, Call Faculty Relations and/or Research Services

http://www.uwo.ca/research/_docs/resources/Eligibility_Guidelines.pdf
Getting started...

1. **Complete TCPS2 Core Tutorial**: [https://tcps2core.ca/welcome](https://tcps2core.ca/welcome)

   *Mandatory* Training for Human Research *(effective October 1, 2020)*

Certificate of Completion must be uploaded to OWL for monitoring purposes (managed outside of the OHRE).

See Western’s Human Ethics **Workshops & Seminars** webpage for more info:

[https://www.uwo.ca/research/ethics/human/workshops/index.html](https://www.uwo.ca/research/ethics/human/workshops/index.html)
Getting started...

2. Familiarize yourself with WREM

*Workshops & Seminars webpage:*

- WREM 101 – online webinar offered biweekly
- WREM Quick Facts Handout

*WesternREM webpage:*

- User Guides, Tutorials, Videos, etc.
Getting started...

2. Familiarize yourself with REB resources

   **Upcoming session:**
   **Remote Consent: Dec 11**
   (registration required)

   **Prior Session:**
   Ask an EO session
   *(provides an overview of pandemic-specific content)*

   **Handout:**
   Top 10 Tips for a Successful REB Application
Getting started...

• Review our Guidelines & Templates
  • Guidelines for Participant Recruitment
  • Remote Consent Guidance Document
  • Sample recruitment templates; Debriefing template
  • NMREB Letter of Information and Consent Guidance Document and Template; Assent Letter Guidance Document and Template
  • Guidelines for Translated Documents
  • Data Security and Confidentiality – Guidance Document
  • Open Access / Open Data guidance document
  • Compensation Guidance Document
Getting started...

3. Imagine yourself as a participant in your study.

4. Think through all logistics of carrying out the project from conceptualization to dissemination and data destruction (e.g., 7 years post-publication per FCA).

5. Read all instructions/questions carefully and respond thoroughly and clearly (the REB must understand everything a participant will experience).
Getting started...

6. Be aware that each REB application is reviewed on a case-by-case basis.

7. What is your research question? One REB application per research question, or set of research questions.

8. Consider how/whether your project may evolve, and incorporate this into initial application, if possible.

9. Study instruments (e.g., interview guide, stimuli, etc.) must be a representative sample, if not complete.
Allow adequate time for review and responses

• Current turnaround times (initial to approval):
  • HSREB: 55 days (FB 68, Delegated 49)
  • NMREB: 41 days

• Determine the most appropriate board (HSREB or NMREB).

• Is Lawson approval needed? (e.g., hospital involvement)

• Full Board review? Check submission deadlines.

• Specific time restrictions? Alert REB ASAP and try to start early.
Ensure completeness and consistency

• Provide sufficient detail regarding study procedures
  • Incomplete submissions will be return un-reviewed.

• Submit ALL study documents and instruments for review.
  • E.g., data collection tools, interview guides, LOI/C, recruitment materials, etc.

• Note: These documents must be in their final form (i.e., no comments, tracked changes, etc.) to be approved.
Initial REB Reviews

EO
Compiles all Recommendations, obtains Chair sign off, sends to PI

PI
Completes WREM Application Form and submits to OHRE

OHRE
Receives form, checks for completeness, assigns EO, Primary Reviewer (Board Member), and Meeting Date

EO + Primary Reviewer/All Board Members
Review application & study documents. Provide feedback ("Recommendations") via WREM

Full Board Meeting
Primary Reviewer summarizes the study, board discusses concerns, makes decision on initial submission

DECISION
1. Approved: No modifications required, proceed to "END"
2. Pending Modifications: Changes required to the submission. Review of the modifications are done at the ORE, not reviewed at another FB Meeting.
3. Tabled: Significant modifications required. Board will re-review application in full following modifications

*Note: If Lawson-affiliated, ReDA application required first. Then, export to WREM.

Initial review: 2-3 weeks
Response: 1-2 weeks
Submitting Responses to REB Recommendations

- Change 1.1 to “Response”.
- Include each REB question/recommendation and your specific response to each in a separate document.
- TRACKED and CLEAN copies of all documents needed and submitted in the appropriate locations.
- MUST delete the old versions.
- Version date (dd/mm/yyyy) in footers that match date entered when uploading document.
Dear REB, thank you for the August 1 review of our submission. Please find our responses below. Documents re-submitted include the LOI and survey.

1. **Q1.4 Please list all study team members.**
   John Smith and Jane Doe have been added to Q1.4.

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**The Good,**

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**the Bad, and the Ugly.**

1. 13.3 Complete.
2. 1.4. Add identifiers. Identifiers added.

1. Complete.
Approval

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

• Secondary Use of Research Data:
  • *REB requirements depend on the character of the data that will be analyzed:*
    • **Anonymous** at time of collection – exempt from REB review (see TCPS2 Article 2.4)
    • **Non-identifiable** at the time of secondary use – REB review, no consent (see TCPS2 Article 5.5B)
    • **Identifiable** (even if not identifiable upon dissemination of secondary findings, or if access to the code is needed to re-identify participants) – REB review, consent needed UNLESS certain conditions are met (see TCPS2 Article 5.5A).
Special considerations

• Multi-Jurisdictional Research:
  • Conducting research at/through other institutions may require additional REB review.
  • Each institution operates differently; be sure to contact the other institutional REB for guidance prior to recruitment.
  • At Western, REB review requirements determined by:
    • Western researchers’ role: Direct vs. peripheral
    • Study activities on campus by external researcher
Special considerations

• Research with professionals (e.g., educators, administrators, etc.)
  • A participant is a participant is a participant (even if low risk, and not vulnerable).
  • Same basic requirements re: recruitment, consent, and confidentiality.
Special considerations

• Need to consider and clearly explain to the REB and participants:
  • Research questions
  • Data collection methods
  • Implications of disseminating results

*Including deception in a study design can complicate these ethical considerations, and requires additional justification and provisions (e.g., thorough debriefing).
Special considerations

- Will participants be exposed to risk beyond what they would encounter in their daily lives? FB review needed.
- If foreseeable risk (even if minimal and/or equivalent to everyday life), indicate this in REB application and alert participants to this in the LOI/C.
- If sensitive topics will be discussed (e.g., eliciting emotional responses), **support resources** and appropriate researcher **training** and/or **response protocol** is needed.
- Report any adverse events to the REB.
Special considerations

• Best practices for recruitment:
  • Recruiting through publicly available contact info?
  • Snowball sampling where Person A shares researcher info with potential participant(s) who can contact researcher directly for more info, if interested.
  • Any influences on participation must be minimized (e.g., voluntary, no affect on employment) and any dual roles mitigated.
  • Privacy and confidentiality must be maintained.
  • REB approves all recruitment materials (e.g., posters, email scripts, telephone scripts, social media posts, etc.).
Special considerations

• Common practices for informed consent:
  • Written consent if face-to-face.
  • Verbal consent if remote (e.g., telephone/video-conferencing).
  • Implied consent for online surveys.
  • Written/verbal assent from participants without capacity to consent.

*NOTES: Informed consent includes
  (a) process, (b) document (LOI), and (c) documentation.
Special considerations

• Best practices for confidentiality:
  • Identifiable information never collected with data; labelled instead by unique ID/pseudonym
  • Identifiable information linked to unique ID/pseudonym through master list; encrypted/physically locked

Remember, participants have the right to request withdrawal of their information if they choose, so researchers have the responsibility to facilitate this, if feasible.
Special Considerations

• Limitations to confidentiality need to be disclosed and mitigated wherever possible:
  • Group-based data collection activities
  • Online research
  • Photography/videography
  • Duty to report

*Note: Explicit consent is required for the use of direct quotes and/or direct/indirect identification (e.g., upon dissemination).
Special considerations

• Research involving K-12 education system:
  • School Board research ethics approval needed as well (typically after Western’s REB approval is received).
  • Be aware of school board submission deadlines, and prepare for Western’s REB approval well in advance.
  • 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?
  • Consider logistics of any in-school activities, confidentiality, voluntariness, and applicable background checks.
Special considerations

• Educational Interventions:
  • Be mindful to include neutral language re: benefits, as these are yet to be determined.
  • If teachers are both participants and administering an intervention, consider impact on teachers’ right to voluntary participation/withdrawal.
  • Be specific with respect to activities ALL students will engaged in vs. study-specific procedures/activities.
  • Be specific with respect to activities taking place in class vs. outside of class time.
Special considerations

• Research with ‘marginalized/vulnerable’ groups:
  • Vulnerability is determined by the research context, as opposed to identifying with a particular group.
  • Special attention is needed, but not all research involving these topics requires Full Board review.
  • Inclusion/exclusion criteria must be methodologically justified.
  • Participants need capacity to consent; otherwise, substitute decision maker or parent/guardian consent needed in addition to participant assent.
  • Creative strategies may be needed depending on the research context/participant sample (e.g., disabilities).
Special Considerations

• Other languages:
  • Translations (English copy for REB review, translated copy for REB records)
    • Attestation letter confirming translations are accurate and complete representations of the English versions.
    • Usually someone outside research team.
  • You may submit translations after English versions finalized to minimize number of translated versions created/submitted.
  • Interpreter? Need confidentiality agreement.
Special Considerations

• Other communication challenges:
  • Literacy concerns?
    • E.g., verbal consent; impartial witness signature
  • Vision/hearing impairments?
    • How will you accommodate to ensure appropriate communication/comprehension?
  • Any barriers to ongoing communication?
    • E.g., longitudinal study involving individuals experiencing homelessness without contact info – how will you locate them for subsequent data collection phases?
Special Considerations

- Participatory and/or community-based research including, but not limited to Indigenous contexts):
  - Read TCPS2 Chapter 9 (Research Involving the First Nations, Inuit and Métis Peoples of Canada)
    - Principles apply to non-Indigenous contexts as well.
  - Outline community engagement activities.
    - Confirm timing and procedures for community-level ethics review.
  - Describe norms, customs, barriers, solutions, etc. pertinent to understanding/reviewing the research plan.
  - Read TCPS2 Chapter 10 (Qualitative Research)
    - Describe emergent nature of research.
Special Considerations

Important Notes:

• Research cannot commence until REB approval (and local permissions) are in place.

• BUT, initial, exploratory discussions to inform the design of the study and/or community engagement activities can occur prior to REB application (see TCPS2 Article 6.11 and 10.1).

• These preliminary discussions ensure the information submitted for review is accurate and culturally appropriate, and that the project is feasible.
Special Circumstances:

• Community collaborations, industry-sponsored research and/or collaborations with companies:
  • Full disclosure is needed in the initial ethics application:
    • Who is the partner?
    • What is their role?
    • To what (if any) data they will have access?
    • Are there any conflicts of interest?
  • Contracts/agreements may be needed between Western and the partner. Consult Research Contracts for more information and/or support generating an agreement: https://www.uwo.ca/research/services/contract.html
Special Considerations

• Use of third party procedures/technologies/cloud-based software:
  • When used to collect/transfer/store identifiable/sensitive information, they need to be evaluated and vetted by the institution.
  • Technology Risk Assessment (TRA; see https://security.uwo.ca/tra/)
  • Recommendation: Arrange institutional review prior to REB application OR expect delays on REB review.

*Not needed if technology is on local hard drive and/or de-identified data only.
Common Tools Approved by the REB

Data Collection and Transfer

• Any tool within Western’s Office 365 Suite or OWL
  • (incl. collaborating with external partners, member-checking, etc.)
• Western’s Qualtrics
• Western’s Zoom
• Pavlovia (contact the REB for TRAC report)
• SPSS
• NVivo
• Dedoose
Common Tools Approved by the REB

Transcription:

- NVivo
- MS Stream (Office 365)
- Zoom (if recording in Zoom; note: transcription records only retained for 7 days)
- Transcription Heroes (professional company)

*The REB needs to ensure participants are informed that a professional transcription service OR software will be used, AND the security/confidentiality measures in place to protect their information.*
Special Considerations

• Research Data Management (RDM):
  • Tri-Agency funding may require RDM strategies as part of grant applications.
  • The REB needs to know researchers’ Data Management Plans (DMP) to ensure they meet ethical standards and participants are adequately informed.

• Western Libraries can help! For more information, see https://guides.lib.uwo.ca/rdm
Special Considerations

• Registries, Publications, and Open Access:
  • If you wish to share any data outside the research team (e.g., in a registry, open access repository, for publication purposes, for other researchers to verify the findings or re-analyze, or for public archiving), this needs to be indicated in the REB application & LOI/C.
  • Stating “no one outside the research team will have access to the study data” will prevent sharing in the future.
In sum...

• There is a lot to consider when preparing for research involving humans, but there are a lot of resources to support you!

• 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?