Successfully Navigating the REB Process at Western: Tips for Researchers in the 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

• **Overview** of human research ethics requirements
• **Submitting REB applications** at Western University
• **Resources** for further learning and support
• **Q&A**
What is Human Research Ethics?

Human research is research conducted with or about people, or their data or tissues, with the sole intention to do good.

Mandal et al., (2011)
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3593469/

Human participant research raises unique and complex ethical, legal, social and political issues. There are three core objectives in human research ethics.

1. To protect human participants.
2. To ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole.
3. To examine specific research activities and projects for their ethical soundness, looking at issues such as the management of risk, protection of confidentiality and the process of informed consent.
Office of Human Research Ethics (OHRE)

• The administrative arm that aids the Research Ethics Board (REB) in the facilitation of the approval and monitoring of research involving human participants (incl. human biological materials).

• Research involving humans conducted by faculty, staff or students at Western University or its affiliated hospitals or research centres/institutes must be reviewed by the REB in accordance with ethical standards.
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
Human Research Ethics

Tri-Council Policy Statement II – Ethical Principles:

• **Respect for persons** (right to choose, autonomy, free, informed and ongoing consent)
• **Concern for welfare** (obligation to do good, benefits outweigh risks)
• **Justice** (fairness and equity, justifiable inclusion, balanced power relationships)

*These guiding principles are all research activities, not just projects requiring REB review.*
When is REB review required?

Are you conducting research with human participants, as defined by the TCPS2?

• “Research” = an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation

• “Human participants” (i.e., “participants”) = individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s)
Can I engage with people for research purposes who are not considered ‘participants’?

- Research activities involving interaction with individuals who are not themselves the focus of the research does not require REB review/approval (TCPS2 Article 2.1).
  - E.g.: Collecting information from authorized personnel to release information in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports, without collecting any observations about them or requesting personal opinions from them.
Can I engage with people for research purposes who are not considered ‘participants’?

• Initial exploratory phases of projects intended to discuss the feasibility of the research, establish research partnerships, or the design of a research proposal do not require REB review (TCPS2 Article 6.11 and 10.1).
  • E.g.: Community engagement prior to the research
What if I am relying exclusively on publicly available information?

- E.g.:
  - Information accessible through the public domain where there is no expectation of privacy
  - Information that is publicly available through a legislated mechanism/regulation and is protected by law
- No REB review needed.
  - See TCPS2 Article 2.2 for more info (e.g., copyright or other legal considerations may apply)
Can I observe people in public spaces?

• Relying exclusively on **naturalistic** observation where there is **no expectation of privacy or any manipulation or intervention** in the environment does not require REB review.
  • Note: Asking questions, engaging in dialogue, etc. would be considered an ‘intervention’ and therefore no longer naturalistic. REB review/approval would be needed in this case.
• See TCPS2 Article 2.3 for more info
What if I have access to anonymous data? Can I use it for research purposes?

• Previously collected **anonymous** data can be used for research purposes without REB review, provided there is no generation of identifiable information (TCPS2 Article 2.4).

• **NOTE:** This does not include coded or anonymized data, which do require REB review, but may or may not require consent (see TCSP2 Articles 5.5A/B).
What about quality assurance projects?

• TCPS2 Article 2.5 indicates projects being conducted for the sole purposes of internal assessment, management or improvement purposes and not academic research do not require REB review.

• Refer to Western’s QA/QI/PE Guidance Document https://www.uwo.ca/research/ethics/human/board_guidelines.html

• To confirmation your project is exempt, submit your project via Western’s research ethics online submission platform, Western Research Ethics Manager (WREM): applywesternrem.uwo.ca
What about engaging in creative practice?

• TCPS2 Article 2.6 indicates creative practices which involve humans that is not academic research does not require REB review. But, arts-based research and research-creation involving human participants may require review.

• Contact our office to discuss if you are unsure if your project requires REB review.
When in doubt, reach out!

Contact our office to discuss if you are unsure if your project requires REB review or meets the exemption criteria.
## Our Staff

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
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<tbody>
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WesternREM

The human research ethics team launched WesternREM, its new online protocol submission platform, on September 7, 2017, replacing ROMEO.

**For up to-date information regarding research during COVID-19 please see our Communication page**

All newly created projects meeting Lawson Health Research Institute criteria must first be submitted here.

If you have any questions or concerns in regards to the ReDA or LORA systems please contact Lawson at lawsonapproval@lawsonresearch.com.

Training Materials

- Online User Guides
- Quick Guides
- Training Videos

Training

Training sessions are continuing to be offered by our office. These sessions will cover the full slate of the ethics submissions processes, including: setting up accounts, adding/removing research personnel, submitting initial studies and post-approval submissions (e.g., amendments, continuing reviews, study closures, reportable events, etc.), general system navigation and where to access training materials.
Our Online Submission Platform: WREM

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

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.

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 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.

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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<tr>
<th>Review Type</th>
<th>Risk Level</th>
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<tr>
<td>Full Board Review</td>
<td>Prospective research &gt; minimal risk</td>
</tr>
<tr>
<td>Delegated Level 1 (DL1) Review</td>
<td>Retrospective Research ≤ minimal risk</td>
</tr>
<tr>
<td>Delegated Level 2 (DL2) Review</td>
<td>Prospective research ≤ minimal risk</td>
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</tbody>
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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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<td>Research &gt; minimal risk</td>
</tr>
<tr>
<td>Delegated Review</td>
<td>Research ≤ minimal risk</td>
</tr>
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</table>

**Minimal Risk:** potential harms are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Examples of when NMREB Full Board Reviews may be needed

- Sensitive topics or procedures increasing risk to participants (e.g., psychological, emotional, social, economic);
- Risky procedures or data management plans;
- Involvement of participants who are vulnerable in the context of the research (e.g., children, individuals unable to provide informed consent, marginalized/disadvantaged groups);
- Novel or controversial research designs and/or procedures that compromise any core ethical principles of research and require full board discussion to determine the most appropriate course of action.
Allow adequate time for review and responses

- Recommendation: Prepare for 2-3 months from the time of submission to the approval date.

- Full Board review? Check submission deadlines on website: [https://www.uwo.ca/research/ethics/human/deadlines.html](https://www.uwo.ca/research/ethics/human/deadlines.html)

- Specific time restrictions? Alert REB ASAP and try to start early.
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 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. **Mandatory** Training for Human Research  
   *(effective October 1, 2020)*

   Certificate of Completion uploaded to OWL.

   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)

   Tip: Existing files? Make sure study team is current!
Getting started...

2. Familiarize yourself with WREM and REB resources

**Workshops & Seminars webpage:**
- WREM 101 – online webinar offered regularly
- WREM Quick Facts Handout
- Intro to Ethics and WREM (video)
- Top 10 Tip for a Successful REB Application

**WesternREM webpage:**
- User Guides, Tutorials, Videos, etc.

**Guidance Documents and Templates:**
(see next slide)
Getting started...

- Review our *updated* Guidelines & Templates:
  - Guidelines for Participant Recruitment
  - Remote Consent Guidance Document
  - Use of Qualtrics for Informed Consent
  - Sample recruitment templates; Debriefing template
  - NMREB Consent Form 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. Consider the *audience* of an REB application and the accompanying study documents.
   - Different purpose and voice from a thesis proposal or grant application

4. Imagine yourself as a participant in your study.

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

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

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

8. What is your research question? One REB application per research question, or set of research questions.
9. Consider how/whether your project may evolve, and incorporate this into initial application, if possible.

10. Describe all intended data collection activities/participant groups/etc.

11. Study instruments (e.g., interview guide, stimuli, etc.) must be complete and finalized (unless a representative sub-sample is justified).
Initial REB Reviews

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

**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.

Initial review: ~3-4 weeks
Response: 1-2 weeks
NMREB Initial Applications
NMREB Initial Application

• Need to consider and clearly explain to the REB and participants:
  • Study team (who is doing what?)
  • How your research questions will be addressed by proposed design/methods
  • Inclusion/exclusion criteria (Q2.15/Q2.16)
    • Ensure consistent with any anticipated communication challenges (Q5.3) and use of translated documents (Q11.1)
  • Screening? Communicated at recruitment/consent?
NMREB Initial Application

• Need to consider and clearly explain to the REB and participants:
  • Consent procedures (incl. logistics: e.g., are participants expected to have printers available?)
  • Impacts on participants (minimizing harms and inconveniences)
  • Implications of disseminating results (How? Where? To whom? How will results affect participants and/or the groups to which they belong?)
Exposing Participants to Risks

- When beyond what they would encounter in their daily lives? FB review needed.
- If any 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.
Secondary Use of Information

• Non-identifiable at the time of secondary use:
  • REB review, no consent (see TCPS2 Article 5.5B)

• Identifiable:
  • REB review, consent needed UNLESS certain conditions are met (see TCPS2 Article 5.5A).

*Initial NMREB app requires clear description of data sources (Q2.3/Q2.4/Q2.5) and justifications for waivers of consent (Q5.1), and/or recruitment/consent communications (Section 4/5).*
Collection of Identifiers

• Collect only what is needed to carry out research
• Ensure consistent and complete (e.g., Q7.2, LOI/C, and data collection tools).
• Best practice = master list to record/store **direct** identifiers, linked only to unique ID code/pseudonym
  • Facilitates withdrawal of data
  • **Indirect** identifiers can be collected with data; justify and ensure informed consent.
Confidentiality Limitations

- Need to be disclosed for fully informed consent, and risks mitigated whenever possible:
  - Group-based data collection activities
  - Online research
  - Photography/videography
  - Duty to report
  - Directly identifying participants upon dissemination
  - Use of direct quotes (even if pseudonymized)
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).
Research involving participants who do not speak/write/understand English

- REB requires both English copies and translated copies (particularly for informed consent).
  - 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.
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?
Participatory and/or community-based research

- Includes, but is 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.
Research Context and Methodological Decisions

- TCPS2 states repeatedly that the onus is on the researchers to justify their proposed approaches to the satisfaction of the REB.
- If you have additional information that has informed how the application has been prepared, explain this.

*You know your research context better than the REB, but the REB is tasked with evaluating the projects according to the TCPS2 framework, so you may receive questions/suggestions in feedback if not pre-emptively acknowledged and justified.
Use of third-party procedures/technologies/cloud-based software (Q2.6)

• When used to collect/transfer/store/analyze identifiable/sensitive information, needs 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.
  • Contact TRAC for information on currently reviewed programs and reports.
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
Sharing data outside the research team

• E.g., Transcription, Registries, Publications, Open Access, Other Researchers, Public Archiving:

  • Must be indicated in the REB application (Sections 8/9) & LOI/C.

• Note: Stating “no one outside the research team will have access to the study data” will prevent sharing in the future.
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 (submit WREM form for confirmation if needed)
  • Study activities on campus by external researcher
External Collaborations

- 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
Recommendations Letters

• You will likely receive feedback for revision.
• Minimize recommendations by:
  • Proof-reading prior to submission (consider asking a friend/collleague to proof-read too);
  • Making use of all current resources; and
  • Asking for help when needed.
Submitting Responses to REB Recommendations

• Change 1.1 to “Response”
• Response letter:
  • *Verbatim* question/recommendation followed by specific response to each in a separate doc.
• Revised Documents:
  • Using the Tracked Changes feature in Word, submit TRACKED and CLEAN copies.
  • **Delete** the old versions.
  • Update version date (dd/mm/yyyy) in footers
  • Enter document version date when uploading documents.
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.

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)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
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</table>
| **Amendment**             | - Modifications to the approved application and/or study documents.  
- Amendments must be approved prior to implementation. |
NMREB Amendments
Changes to approved project WHEN investigating the **same** research question(s)

- Additional recruitment source/participant pool
- Modified measures/stimuli
- Changes to study team
NEW application may be required when...

- New scope of research
- Introduction of significant deception/risks
- Change to conflict of interest
Tips!

• Q1.6 – select ALL that apply
  • This populates additional sections of the form.

• Upload applicable materials where prompted:
  • The form has been specifically designed to probe you to submit various materials.
  • Only if there is no predetermined checkbox or place for it, select ‘other’
Tips!

- Changing study team members:
  - When removing someone, ‘search over’ that person and replace with another member of the study team.
  - If no other member of the study team, select ‘no’ after the last person list.

Always ensure all study team members have access to WREM AND Project Owner is current (required for updating the forms when changes are published).
Continuing Ethics Reviews and Study Closures
CERs and Study Closures

• Keep track of the expiry dates and submit CERs on time.
  • Do not rely on courtesy reminders.
  • Avoid lapse in approval (and the possibility of not being able to use data collected during lapse).
  • PIs are unable to receive REB review on new applications if other projects are outstanding.

• Submit a Study Closure when your project is complete.
• Be clear and consistent re: the number of participants consented (the numbers reported should equal out).
• Participant observation: Be as specific as possible (noting this may be an estimate, depending on the approved consent procedures).
Online Resources

➢ Complete TCPS2 Core Tutorial: https://tcps2core.ca/welcome

➢ Go to https://www.uwo.ca/research/ethics/human/index.html

➢ Use our resources and presentation material
  ● Improving your Ethics Application and Minimizing Recommendations
  ● Tips and Tricks for Writing your Ethics Application
  ● Top 10 Tips for a Successful REB Application
  ● WREM Quick Facts

➢ Use our guidelines and templates

➢ Use the Correspond button in your file on WREM to contact the Ethics Officer directly.

➢ Contact us: Email: ethics@uwo.ca

➢ In Person: 5th Floor, Support Service Building, Rm 5150
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?