Disclaimer

The information provided in this presentation is consistent with the current policies and guidelines laid out within our office, the Research Ethics Board, the University and the TCPS2 and are subject to change.

This presentation is designed to provide a general orientation to the ethics submission process. Ensure to visit our website and consult with our staff for specific enquiries as needed.
Writing Successful Ethics Applications in Western's Faculty of Education

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Overview

• Setting up for success
• Key considerations when designing studies and preparing applications
• Special circumstances in educational research
• Key tips to avoid common errors
• Ongoing review
• Questions
Setting up for Success

- Complete TCPS2 CORE tutorial: https://tcps2core.ca/login
- Start application early.
- Familiarize self with WREM online application submission platform (applywesternrem.uwo.ca).
- Refer to WREM Quick Facts and Top 10 Tips handouts.
- Include full disclosure of study procedures and collaborations with external parties.
Key Considerations

• 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)
Key Considerations

• Develop a protocol:
  • For clarity and consistency, prior to starting your WREM submission, write a stand-alone protocol and think about how you will operationalize your study.
    • i.e., outline the ‘who, what, where, when, and how’
    • Upload to Q2.7.
  • Remember that logistical issues exist even in minimal risk studies.
Key Considerations

- Think about all of your different participant groups and/or study activities.
  - Describe each in all relevant sections of application (study procedures, recruitment, consent process).
  - Consider using tables/figures/flow charts (Q2.6).
Key Considerations

• Anticipate questions:
  • The REB needs to see/experience what a participant will see/experience, and needs to understand what is being proposed in order to know what is being approved.
  • Is there a specific reason for doing something a particular way? Do you have additional details based on previous experiences? The REB needs to understand why a particular approach is being proposed, especially if there are ethical implications.
Key Considerations

• Privacy/confidentiality:
  • How are you obtaining contact information for participants?
  • How are you protecting participants’ data?
  • How will information be disseminated? Who will have access?
    • Other participants? (focus groups, sorting tasks)
    • Photographs for photovoice? Student artifacts?
    • Theses materials? Open access requirements?
    • Third parties?
Key Considerations

- Communication with participants throughout the lifecycle of the project:
  - Participants need to be fully informed of study procedures/commitments prior to consenting
    - E.g., table of timelines/expectations at each stage for multi-activity and/or longitudinal projects
  - Member-checking? How?
  - Compensation? How?
  - Debriefing? How?
  - Email not secure for data (WTS recommends OWL or SharePoint)
Key Considerations

• Implications of interactions with researchers:
  • E.g., personal, sensitive topic?
    • Ensure adequately equipped to respond appropriately and be prepared to provide resources/supports.
  • E.g., inconveniences? (e.g., parking, travel, time)
    • Are you able to off-set any of these?
Special Circumstances:

- Research in classrooms:
  - School board approval
  - Outline process for recruiting within schools
    - E.g., communication scripts to principals/teachers, how will you minimize influence to participate?
  - Recruitment information to parents/guardians
    - E.g., letter of information and consent form) vs. children (verbal script? Assent letter)
  - How will forms be returned protecting students’/parents’ privacy/confidentiality
    - E.g., provided envelopes and return to teacher or office/dropbox
Special Circumstances:

- Online research:
  - Social media recruitment
    - Which sites? Whose accounts? Private group? (moderator permission needed)
    - Communications only through private messaging/email; submit scripts for approval
  - Data collection tools
    - What online platforms are being used? What are the security features of these tools?
    - Who will have access to the information collected online? Full disclosure of this needed in LOI/C.
    - Western Technology Services may need to be consulted which can delay review times.
Special Circumstances:

- Industry-sponsored research and/or collaborations with companies:
  - Full disclosure is needed in the initial ethics application:
    - Who is the company?
    - What is their role?
    - To what (if any) data they will have access?
    - Are there any conflicts of interest?
  - Contracts may be needed between Western and the company. Consult Research Contracts.
Special Circumstances:

- Snowball sampling:
  - Researcher provides research information (e.g., poster? email?) to a third party (e.g., current participant, organization gatekeeper, etc.) to a potential participant; potential participant contacts researcher directly for more information.
  - Protects the privacy/confidentiality (i.e., identity/contact information) of potential participants, and promotes voluntary participation (i.e., they only contact the researchers if they are interested).
Special Circumstances:

• Recruiting through people in a position of power/influence (e.g., teachers, employers):
  • Ensure it is communicated that participation is voluntary, participation (or not) will be kept confidential and will not have any impact on [education, employment, etc.]
  • When appropriate, a person who is not in a position of authority should forward the information.
Special Circumstances:

- **Observations:**
  - Public setting, naturalistic (no consent required)
  - Private, expectation of privacy, manipulation of environment, or direct interactions (consent required; how will you obtain? Need scripts)

- **Photovoice:**
  - Training/guide for participants
    - Ethical protocol re: privacy/confidentiality of people who they photograph
    - Additional LOI/Cs?
    - Photo release forms?
Special Circumstances:

• 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 (though for low-risk studies where project team member fluent in other language, this can be accepted).
  • Submit translations after English finalized to minimize number of translated versions created/submitted (indicate this in Q4.5).
  • Interpreter? Need confidentiality agreement.
Special Circumstances:

- Other communication challenges:
  - Literacy concerns?
  - E.g., verbal consent; impartial witness to sign consent form
  - Capacity concerns?
    - How will you determine capacity?
    - How will you obtain consent?
      - E.g., substitute decision maker required to provide consent; participant provides assent
  - Vision/hearing impairments?
    - How will you accommodate to ensure appropriate communication/comprehension?
Special Circumstances:

- Other cultures:
  - Need to inform NMREB of special considerations needed for these participants.
  - Read TCPS2 Chapter 9 (Research Involving the First Nations, Inuit and Métis Peoples of Canada)
    - Principles apply to non-Indigenous contexts as well
  - Community engagement needed.
  - Select ‘community-based research’ in Q2.3.
Key Tips (administrative):

• Follow all instructions:
  • Read questions carefully, review the online guides (help tab), use help texts (blue i icon).
  *contact us if anything is unclear*

• Ensure project team members are added appropriately:
  • Application section 1 (including person creating application)
  • Add ROLE (action tiles on left side of screen)
  • PI must sign-off (section 13)
Key Tips (administrative):

- Describe all logistics/feasibility of the project from a participant’s perspective
  - E.g., how are you going to access your participants? What is expected from them during the project? What are the anticipated time commitments? Where will the study activities occur? Etc.
- ...from the researcher’s perspective
  - E.g., step-by-step details on study activities and data handling, etc.
Key Tips (administrative):

• Provide consistent information across sections of application/study documents:
  • Proofread application and study documents prior to submitting (initial & response).
  • Ensure details accurate and consistent.
  • Have a friend/family member read application and identify errors/gaps.
Key Tips (administrative):

• Include complete and appropriate information in study documents:
  • Use templates/guidance documents in WREM system and include all relevant information.
  • Read participant-facing documents from a participant’s perspective (e.g., what would you want to know?).

Note: Majority of recommendations pertaining to LOI/C are due to missing required details and statements for participants to provide informed consent. Following the relevant LOI/C Guidance Document is the best chance for minimizing recommendations.
Key Tips (administrative):

• Correctly upload documents:
  • Do not include ‘clean’ in the title.
  • Choose an appropriate document name as it will appear on your approval letter.
  • Include version dates/numbers in the footer of your documents.
  • Ensure the version date added in the upload window is consistent with the version date in the footer of the document.
Key Tips (administrative):

- Correctly respond to recommendations:
  - Create a response letter:
    - Copy/paste REB recommendations and respond to each individual question/comment, showing how it was addressed in the application/document.
  - *Track* all changes in documents and update version date. Save tracked copy.
  - Accept all changes and save ‘clean’ copy.
  - Upload tracked copies to Section 12.
  - Upload clean copies in place of the originally submitted documents (e.g., Q4.3 – LOI/C) and delete the original.
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.

The Good, the Bad, and the Ugly.

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

1. Complete.
Use Your Resources & Reach Out

REB Website

Contact Information

Templates

News & Updates

Guidelines
Initial Reviews

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

**START**

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

PI
- Completes WREM Application Form and submits to OHRE
- PI

EO
- Once all Recommendations are complete, Chair signs off, Approval granted to PI
- EO

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

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

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

DECISION
## 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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<tbody>
<tr>
<td><strong>Amendment</strong></td>
<td>• Modifications to the approved application and/or study documents.</td>
</tr>
<tr>
<td></td>
<td>• Amendments must be approved prior to implementation.</td>
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<tr>
<td><strong>Reportable Events</strong></td>
<td>• Protocol Violation/Deviation = unapproved study activities</td>
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<td></td>
<td>• Serious Adverse Event = harmful outcome to study participant</td>
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<td></td>
<td>• FYI = minor updates to REB</td>
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<td></td>
<td>• Data Safety Monitoring Board/Committee (DSMB/C) reports</td>
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<td></td>
<td>• Participant complaints/privacy breaches*contact REB prior to</td>
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<tr>
<td></td>
<td>submitting reportable event in WREM</td>
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<tr>
<td><strong>Continuing Ethics Review</strong></td>
<td>• Annual update required for studies extending beyond one year.</td>
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<tr>
<td>(CER)</td>
<td>• Receipt of CER approval notice required for study continuation.</td>
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<tr>
<td><strong>Study Closure</strong></td>
<td>• End of study report required when there is no further participant</td>
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<tr>
<td></td>
<td>involvement, and all data collection, clarification and transfer is</td>
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<td></td>
<td>complete (including access to participants’ medical record).</td>
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Questions?