



Western Research

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Hot Topics in Human Research Ethics

May 9, 2019

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Today's Agenda

- Multi-jurisdictional Guidelines
- Pedagogical Guidelines
- Cadaveric Sub-Board
- QA/QI and PE Project Exemptions
- News
 - Protocol Requirements
 - TCPS3 update

Multi-jurisdictional Research Guidelines

Multi-jurisdictional Research



Western's REBs are responsible for ethical oversight for research conducted by Western own faculty, staff and students, and research conducted by external researchers using Western's resources.

Western's formal REB oversight IS required when the Western affiliated researcher:

1. Has direct involvement in the project (i.e., recruitment and consent, data collection, analysis/storage of identifiable information), regardless of study location;
2. Holds the research grant (regardless of study location or the researcher's specific role);
3. Has a conflict of interest in the project (e.g., financial gain, commercialization);
4. Is conducting the project as part of their academic degree (e.g., Honour's thesis, Master's thesis, PhD dissertation, or equivalent), regardless of study location.

Western's formal REB oversight is generally NOT required when the Western affiliated researcher only has a peripheral role on an external project.

- Conceptual development
- Recruitment without consent*
- De-identified analysis
- Manuscript review
- Knowledge user not directly involved

Unsure?

WREM

Determining REB Oversight for Peripheral Collaborations

Before completing this form, be sure to review Western University's Guidance Document: [Multi-Jurisdictional Research](#) posted on the [Office of Human Research Ethics](#) website.

If you are unsure whether a WREM application is needed, please complete the following form, and submit this signed document as an email attachment to ethics@uwo.ca, with all relevant materials (approval letters, study documents, protocol, etc.).

Western Affiliated Investigator Name: _____

Western Affiliated Investigator Department/Faculty: _____

Study Title: _____

Collaborator(s): _____

Collaborating Institution(s): _____

Study Summary:

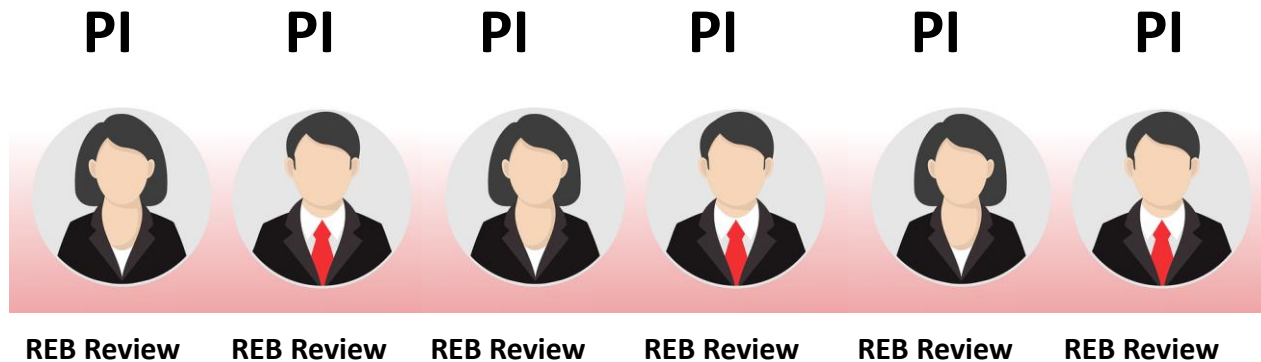
Describe the Western affiliated investigator's specific role in the project:

Researchers not affiliated with Western

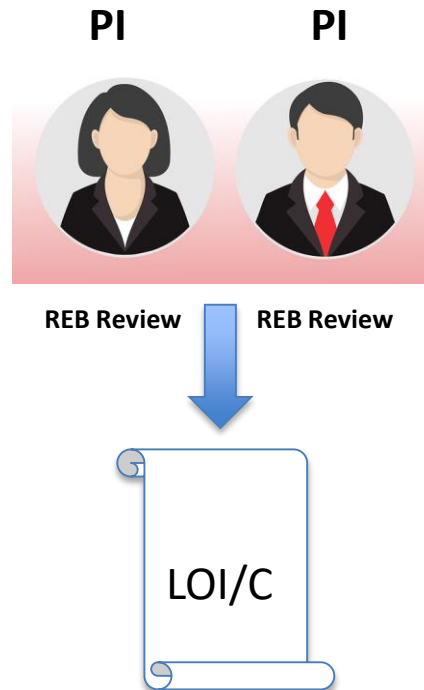
- Submit via **email**, institutional approval letters and approved study materials for administrative review (protocol, LOI/C, data collection, recruitment etc.).
- Issue a no-objection letter

Tips for Submitting Multi-Jurisdictional Research for Western's REBs review/approval

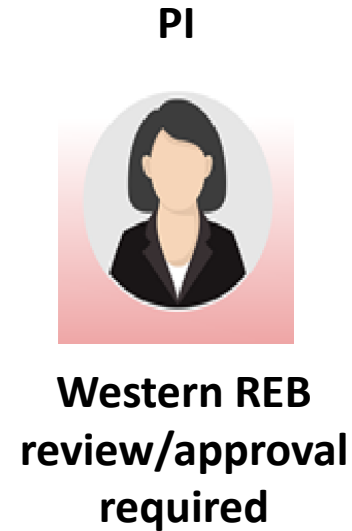
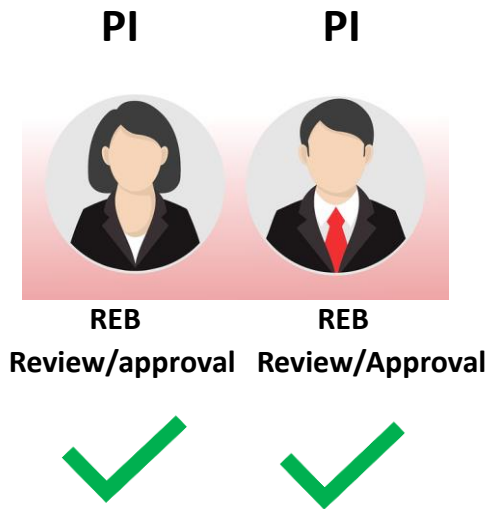
Scenario #1: Western affiliated researcher collaborating with researchers at other institutions where each PI is responsible for one local site.



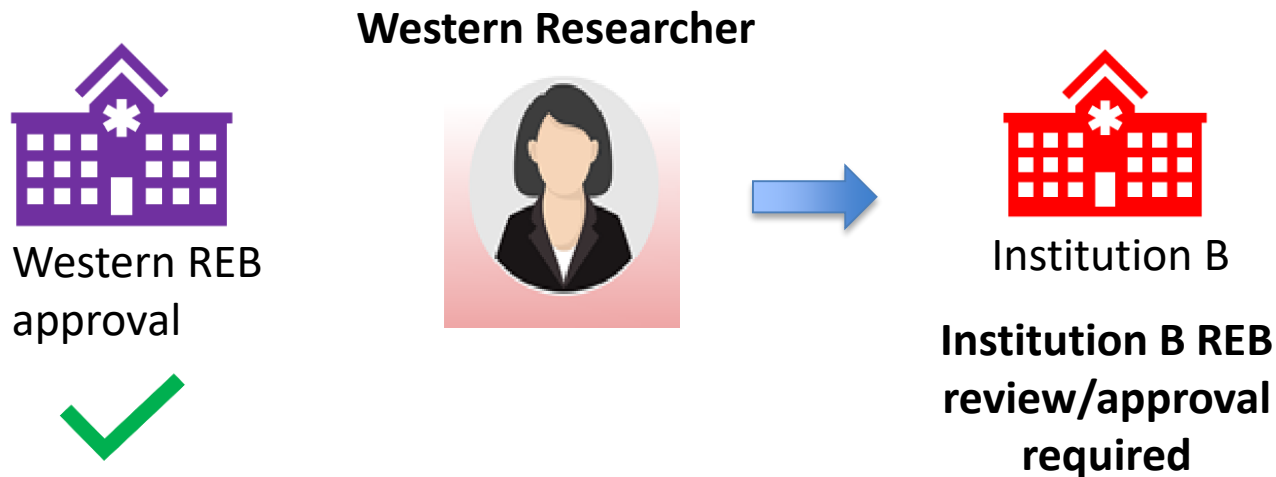
Scenario #2: Western affiliated researcher collaborating with researchers at other institutions using one LOI/C.



Scenario #3: If a project has already received REB approval at another institution and also requires Western's REB oversight.



Scenario #4: If Western REB oversight is needed on a project that will need to be submitted to another REB (e.g., Western researcher collecting data at another institution).



Pedagogical Research Guidelines

Category 1: Research requiring REB review

- Research is defined as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation” (TCPS2, Article 2.1).
- Measures to disseminate results: e.g., publication , thesis/dissertation, KT/mobilization strategies, etc.)

Includes:

Class projects and activities which are intended to reflect the definition of “research” per TCPS2, Article 2.1; and Theses or equivalent research projects (e.g., independent study projects).



Category 2: Course-based pedagogical projects

- Activity embedded within context of course work
- Primary intention is to provide students with research skill practice
- Results will be reported in graded work to meet course requirements only
- Process of data collection is still systematic and rigorous
- The data will not be presented as “research” (TCPS2, article 2.1)
- **Benefit:** student



REB Review Requirements

➤ TCPS2, article 6.12

oversight can be delegated to non-REB members and these projects MUST be reported to the REB

- The REB delegates review of individual student projects to the course instructor.
 - The onus is on the instructor to review and approve all student projects.
- The course instructor submits a Pedagogical Research application for REB acknowledgement.
 - Can be renewed with a continuing pedagogical review application. Must be reported to the REB for closure when done.

Category 3: Professional Skill Development

- Vocational skill development or job-related training within standard educational interactions (student to student, nurse to patient etc.)
- May include research techniques (surveys, interviews, observations etc.) but data will not be analyzed.
- No intentions to produce new knowledge which would be of benefit outside the specific organization within which the skills are being developed
- Assignments would not reflect research standards
- **Benefit:** Student
- **NOT considered research, No REB oversight**

Community-Engaged Learning

- Students matched with community partner (e.g., organizations) and projects may fall in Categories 1-3 as part of practicum.
 - Course instructor is responsible for confirming the extent of REB oversight.

Cadaveric Sub-Board (CREB)

Cadaveric Sub Board

TCPS2: Collection and use of human biological materials requires REB review.

Current process

- Cadaveric material obtained through Body Bequeathal program is reviewed by the Dept. of Anatomy and Cell Biology.
- Cadaveric material obtained through other means is reviewed by the HSREB

New process (by beginning 2020)

- HSREB will delegate review of all cadaveric material to the Cadaveric Research Ethics sub-Board (CREB)
- CREB documents and reports to the HSREB

Quality Assurance/ Improvement and Program Evaluation

QA/QI and PE

➤ TCPS2, article 2.5

- First consultation should be guidance document
 - The checklist serves as record
 - Western's REBs do not issue waivers routinely

Current process

- If researchers are unsure, submit a complete delegated WREM application

New process (to begin in 2020)

- checklist and application for QA/QI and PE exemption in WREM.



Protocol Requirements

Protocols / Research Plans

*Complete description of the project

Importance:

1. It encourages adequate consideration and planning of project detail before they begin (and before submission to the REB);
 2. It provides the basis for funding or human research ethics applications
 3. It acts as a record and reminder for students and their supervisor (co-investigator or collaborators) of the initial project aims and stated procedures. This record also enables them to monitor the progress of the project
-
- Mandatory September 1st, 2019 for HSREB (highly recommended for NMREB)
 - See guidance document for direction

TCP3 updates

TCPS3 Updates

- **Published in May 2019**
- Chapter 9 (Indigenous Research)
 - More guidance on what REBs need to think about (e.g., is the appropriate level of engagement happening)
- Chapter 11 (Clinical Trials)
 - Update CT definition
 - Expand the scope
- Updated guidance on REB exemptions (e.g., pedagogical research)
- Guidance document around how to deal with incidental findings
- A new platform for training will be introduced in the fall

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