



Western
Research

Research Ethics & Compliance Office

(topic: REB process overview)

Today's Agenda



Research Ethics and Compliance Office (RECO)

Western Research



What is Human Participant Research?

Research = an undertaking intended to **extend knowledge** through a **disciplined inquiry or systematic investigation** (TCPS2).

Participant = **an individual whose data, biological materials, or responses** to interventions, stimuli, or questions by a researcher are **relevant to answering the research question(s)** (TCPS2, pg198). Also referred to as a “human participant,” and in other policies/guidance as “subject” or “research subject.”

These types of projects **may** be exempt from REB review.

5 exemption categories:

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

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.

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. Ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole.
3. 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.

Keep in mind...

- Ethical principles:
 - **Respect for persons** (right to choose, autonomy, free, informed and ongoing consent)
 - **Beneficence** (obligation to do good, benefits outweigh risks)
 - **Justice** (fairness and equity, justifiable inclusion, balanced power relationships)

Office of Human Research Ethics (OHRE)

The Office of Human Research Ethics (OHRE) facilitates the Research Ethics Board (REB) manage the approval and monitoring process for research involving human participants.

All 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 external ethical standards:

- Federal (e.g., TCPS2, ICH GCP, HC, FDA)
- Provincial (e.g., PHIPA, FIPPA, PIPEDA)
- Local institutional requirements (e.g., MAPP 7.14, Lawson/hospital policies).

How We Do It

Our Boards

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	Prospective 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.

Important Dates

- **Full Board Review**
 - Submission deadlines and corresponding meeting dates are available online
(HSREB: twice/month; NMREB: once/month)
 - Submissions deadline is by 12 noon on the deadline date
- **Delegated Review**
 - No submission deadlines
 - Reviewed ~2-4 weeks from the date they are determined to be complete (dependent on volume)

The Review Process

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

REB Application Forms

Initial HSREB or NMREB Form

this is the main application form to be used for all submissions for research ethics approval.

Multijurisdictional Form

Used to help researchers determine if oversight by Western's REB is required. See Multijurisdictional guidance document

QA/QI/PE Form

If you are seeking clarification of your project being considered Quality Assurance (QA), Quality Improvement (QI) or Program Evaluation (PE), and therefore not requiring REB oversight, you will be required to fill out this form. See QA/QI/PE guidance document to determine if your project is research or not.

Pedagogical Form

All pedagogical projects considered to fall within Category 2, as per the Student Research and Pedagogical Activities guidance document, will be required to submit a pedagogical application form. See Pedagogical guidance document

Cadaveric sub-REB Form

All human biological material obtained through the body bequeathal program that will be used for research purposes will be required to use this form.

Initial HSREB or NMREB Form

Pedagogical Form

Cadaveric sub-REB Form

Post Approval Forms –sub forms to the main application form

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).

Home > Oversight & Compliance > Human Ethics > WesternREM

Oversight & Compliance

Human Ethics

- WesternREM
- Workshops and Seminars
- Guidelines & Templates
- Board Deadlines & Timelines
- Contact Us
- Communications & Memos

Animal Ethics

Research Integrity

Research Safety

Controlled Substances

Controlled Goods

Conflict of Interest

Funded Research Management

WesternREM Login

WesternREM



WesternREM

The human research ethics team launched WesternREM, its new online protocol submission platform, on September 7, 2017, replacing ROME0.

Note: If you are not currently receiving memos that are sent out by the team but would like to, you can sign up [HERE](#) to join our mailing list.

****For up to-date information regarding research during COVID-19 please see our [Communication](#) page****

> WREM Login

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.

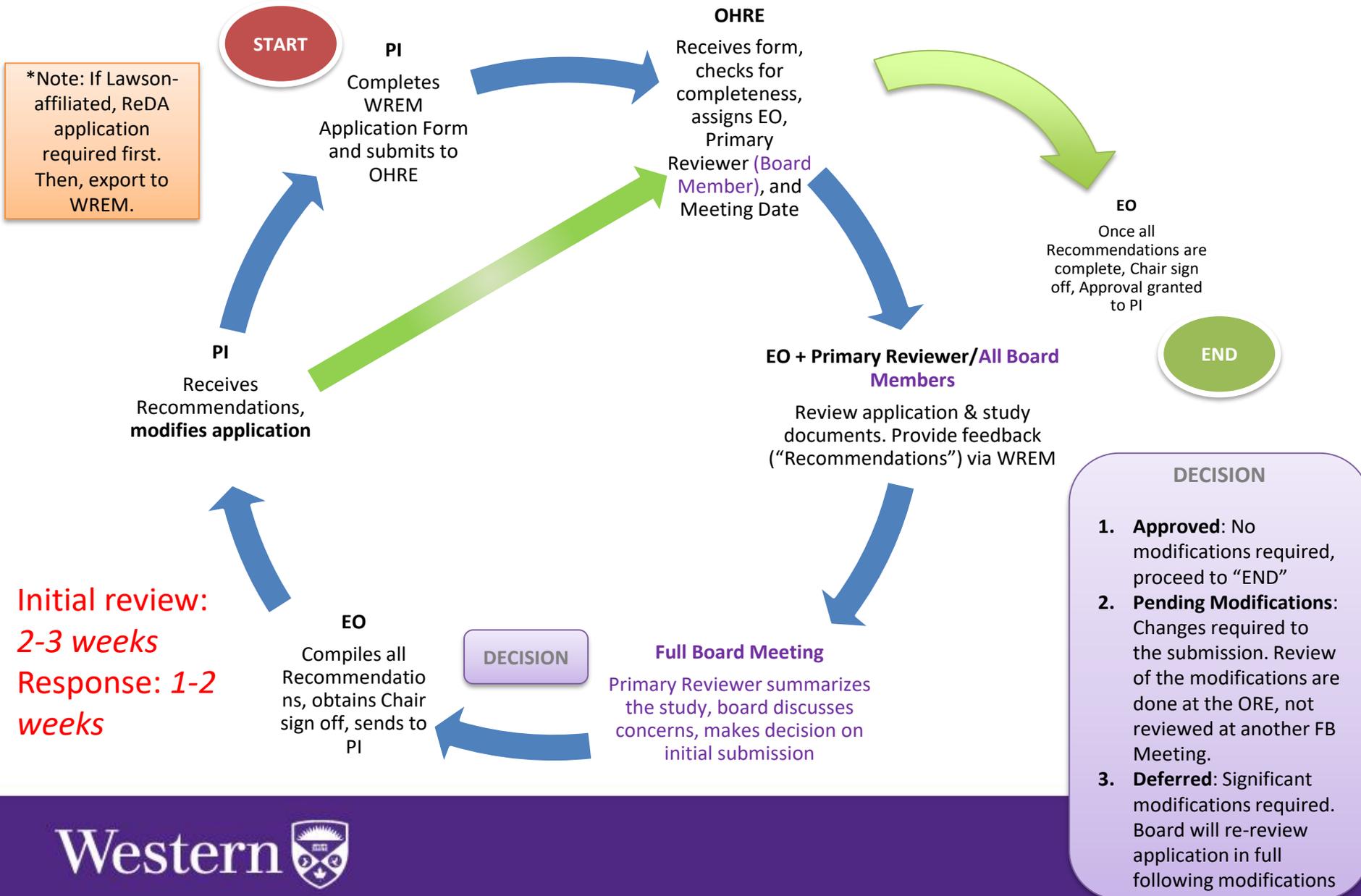
Training Materials

- ▶ [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.

Initial REB Reviews



Helpful Information

Who can be a PI?

- **Those who are eligible to hold a research account**
- Individuals are deemed eligible based on their job requirements.
- 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

WESTERN & LAWSON RESEARCH

Welcome to Research Approval for
Western University Research Ethics Board and
Lawson Health Research Institute



If your study involves human participation but **DOES NOT** meet the [Lawson approval criteria](#), you must submit your study directly with



If your study meets **AT LEAST ONE** of the [Lawson approval criteria](#), you must submit your study first with



Western REB *versus* Lawson Health Research Institute Roles

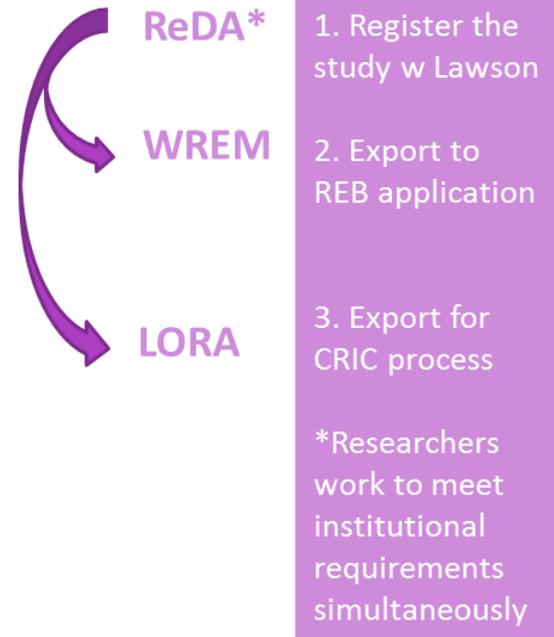
When anyone on the research team will a) rely on their hospital professional credentials, b) use any hospital resources, or c) conduct research at a Lawson-affiliated facility

Then, Lawson approval is required.

Lawson is a separate entity from Western's Research Ethics Boards (REBs) and the Office of Human Research Ethics. However, applications are linked between Western and Lawson using our online application systems.

Lawson approval is multifaceted. REB oversight is delegated to Western's REBs (or another Board of Record) but ultimately forms only one component of institutional approval. Lawson oversees contracts, training, and Clinical Research Impact Committee approval (CRIC). Lawson manages these approvals via ReDA (overall) and LORA (for CRIC).

Western's REBs consider Lawson SOPs, DIERs, contracts, and hospital Privacy Office comments in their reviews but is ultimately **independent from Lawson**. Western's REBs manage applications via Western Research Ethics Manager (WREM). Western's REBs have their own guidelines, templates, and timelines to support researchers.



westernlawsonresearch.ca
Lawson Policy RES017 2016-05-01

Allow adequate time for review and responses

- 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 if time sensitive.

What were common reasons for delay?

- Initial applications are submitted incomplete
- Institutional policies are not followed.
- Inconsistencies and lack of clarity.
- Research not fully conceptualized and logistics not fully in place prior to submission.
- Ethical soundness.
- Scientific soundness.
- Lack of PI oversight.

Approval

Do **NOT** start any research activities until you have received an REB Approval Notice



Date:
To:
Project ID:
Study Title:
Study Sponsor:
Application Type:
Review Type: Full Board/Delegated
Meeting Date/Full Board Reporting Date:
Date Approval Issued:
REB Approval Expiry Date: |

Dear Dr.

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. **All other required institutional approvals and mandated training must also be obtained prior to the conduct of the study.**

Documents Approved:

Document Name	Document Type	Document Date	Document Version
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Documents Acknowledged:

Document Name	Document Type	Document Date	Document Version
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No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

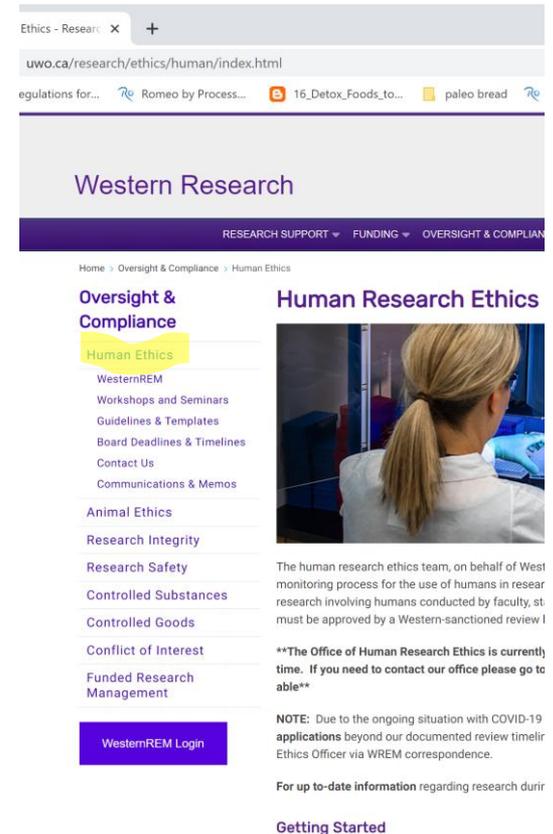
The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TTC Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Use Your 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
- **Contact us: Email: ethics@uwo.ca**
- **In Person: 5th Floor, Support Service Building, rm 5150**



The screenshot shows a web browser displaying the Western Research Ethics website. The browser's address bar shows the URL [uwo.ca/research/ethics/human/index.html](https://www.uwo.ca/research/ethics/human/index.html). The website header includes the text "Western Research" and navigation menus for "RESEARCH SUPPORT", "FUNDING", and "OVERSIGHT & COMPLIANCE". The main content area is titled "Human Research Ethics" and features a sidebar with a list of links: "Oversight & Compliance", "Human Ethics", "WesternREM", "Workshops and Seminars", "Guidelines & Templates", "Board Deadlines & Timelines", "Contact Us", "Communications & Memos", "Animal Ethics", "Research Integrity", "Research Safety", "Controlled Substances", "Controlled Goods", "Conflict of Interest", and "Funded Research Management". A prominent blue button labeled "WesternREM Login" is visible. To the right of the sidebar, there is a photograph of a woman in a white lab coat and a text block that reads: "The human research ethics team, on behalf of West monitoring process for the use of humans in resear research involving humans conducted by faculty, st must be approved by a Western-sanctioned review I". Below this, a note states: "**The Office of Human Research Ethics is currently time. If you need to contact our office please go to able**". At the bottom, there is a link for "Getting Started" and a note about COVID-19: "NOTE: Due to the ongoing situation with COVID-19 applications beyond our documented review timelir Ethics Officer via WREM correspondence." and "For up to-date information regarding research durir".

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