# Research Ethics: Respectful and Responsible Scholarship on Education

**October 9, 2024**

**Dr. Trevor Bieber, PhD**
Research Ethics Officer
(Non-Medical REB)
tbieber2@uwo.ca

Western

# Plan

1) Why are there research ethics requirements?
2) Research Ethics in Canada: TCPS2-2022
3) Do I need to submit? Exempt and Non-Exempt Activities Under TCSP2
4) TCPS2 in Action: Western's REBs
5) TCPS2 in Action: Office of Human Research Ethics (OHRE): Supporting REBs and Applicants
6) Submitting to the REB: Application Forms in WREM

# Why do governments, Like the Government of Canada, Impose Research Ethics Requirements?

**Because some academics did horrifying things to people in the name of research.**

# Research Ethics Atrocities

- **U.S. Public Health Service Tuskegee Syphilis experiment** (1932-1972) - Film: Miss Evers' Boys (1997)
- **Henrietta Lacks' cell line** (1951) – Book and Film: The Immortal Life of Henrietta Lacks (2010)
- **Stanley Milgram's obedience to authority experiment** (1961) - Film: Experimenter (2015)
- **Philip Zimbardo's Stanford prison experiment** (1971) - Film: The Stanford Prison Experiment (2015)

# Research Ethics Atrocities CANADA

**Truth and Reconciliation Commission: Final Report, Volume 1 – Part 2.**

- Documents 8 research studies conducted on students attending Residential Schools between 1940-1980
  - Put students at **unnecessary risk**
  - **No parental consent**, sometimes **students not informed**
- Researchers and school principals claimed consent was not needed because they knew better than Indigenous peoples due to racial superiority and expertise
- All (except 1) occurred after the Nuremburg Principles adopted in 1948
- Some experiments **denied basic nutrition and dental care to students**
- **Experimental** use of **novel treatments for tuberculosis**.
- Canada Food Guide was, at least partly, built upon unethical research carried out in Residential schools.
- Conducted by Canadian researchers publishing in journals



TRC Report, Vol1: Part2, pp. 227-235; 252-292
https://www.cbc.ca/radio/unreserved/how-food-in-canada-is-tied-to-land-language-community-and-colonization-1.5989764/the-dark-history-of-canada-s-food-guide-how-experiments-on-indigenous-children-shaped-nutrition-policy-1.5989785

# Responses to Research Ethics Atrocities

- Nuremberg Code (1948) – after medical experiments on concentration camp prisoners without consent: *voluntary participation* and *informed consent*
- Thalidomide (1962) – drug manufacturers prove effectiveness of products to FDA
- Declaration of Helsinki (1964) – WMA Good Clinical Practices established
- Belmont Report (1979) basic ethical principles
- Tri-Council Policy Statement (1998) (Revised 2018 & 2022)

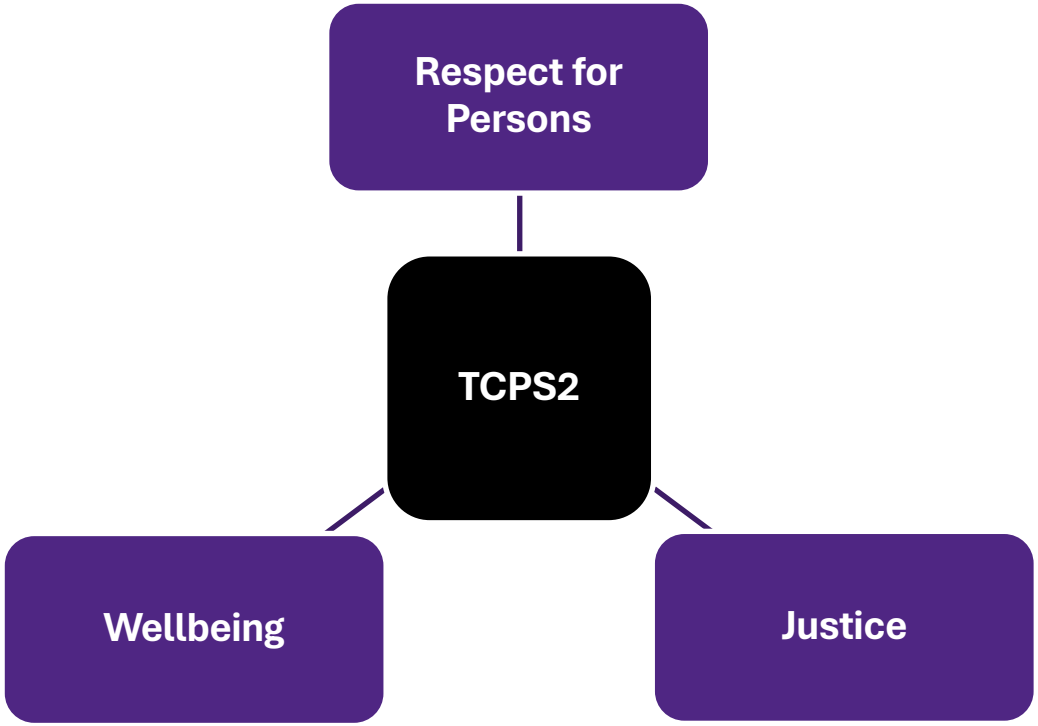
# Research Ethics in Canada: TCPS2-2022: Core Principles

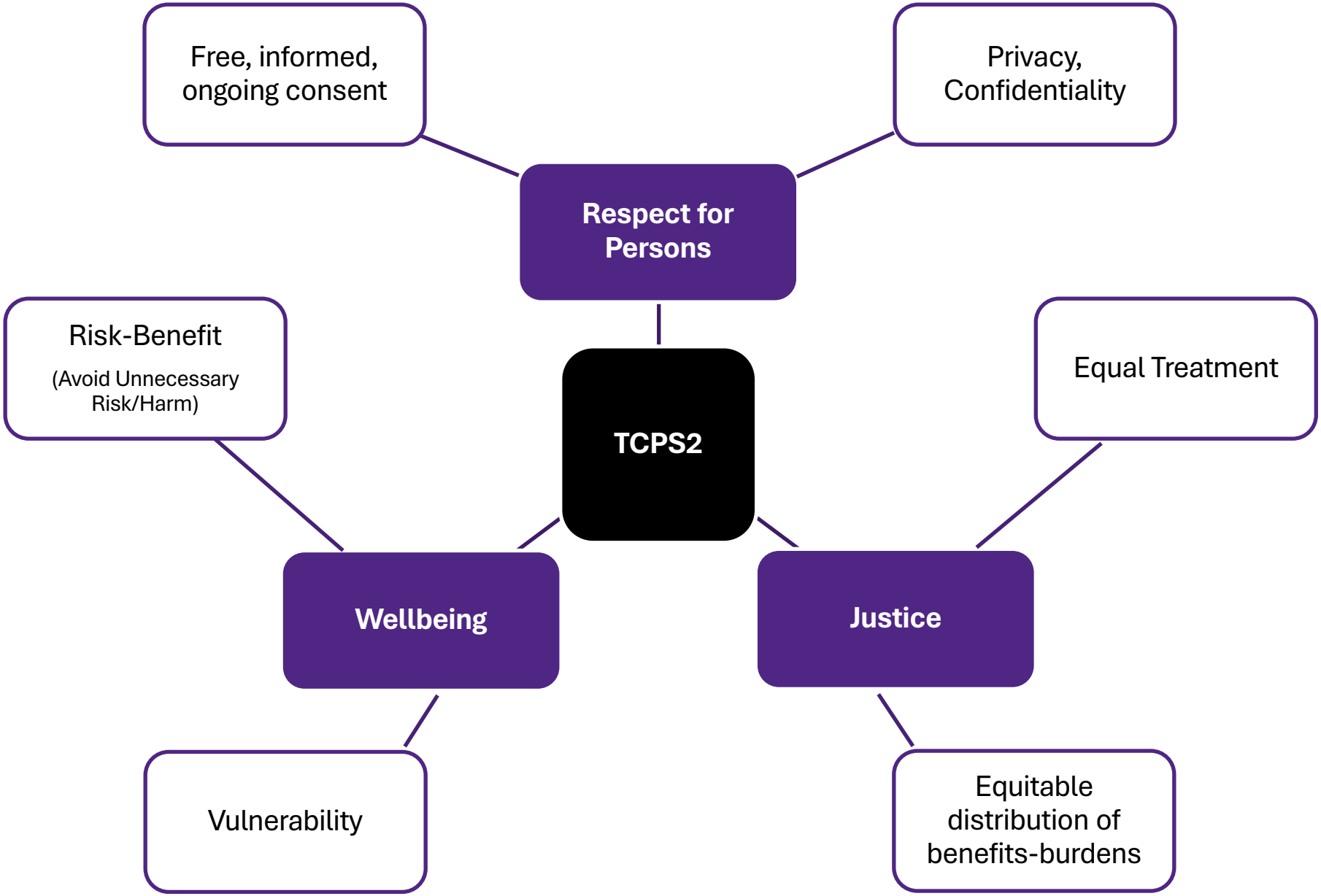
# Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

TCPS 2 (2022)

https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

# TCPS2:
# Three Core Principles


Respect for Persons
TCPS2
Wellbeing
Justice


Free, informed, ongoing consent
Privacy, Confidentiality
Respect for Persons
Risk-Benefit
(Avoid Unnecessary Risk/Harm)
TCPS2
Equal Treatment
Wellbeing
Justice
Vulnerability
Equitable distribution of benefits-burdens

"The importance of research and the need to ensure the ethical conduct of **research requires both researchers and REB members to navigate a sometimes difficult course between**

**the two main goals of**
**[1] providing the necessary protection of participants**
**and**
**[2] serving the legitimate requirements of research.**

The **three core principles** that express the **value of human dignity** provide the **compass** for that **journey**. Their application will help **ensure that a balance between these two goals is maintained**.

Applying the core principles will also **maintain free, informed, and ongoing consent throughout the research process** and **lead to sharing the benefits of the research.** These results will help to build and maintain the **trust** of **participants** and the **public** in the research process."

*(TCPS2-2022, Ch. 1B, "The Core Principles – Conclusion")*

# Operationalizing TCPS2 in Research Projects

- **Recruitment Procedures:** informative, accurate, non-coercive, inclusive
- **Consent Procedures:** full *initial* disclosure to allow fully informed consent (Letter of Information and Consent), ongoing, non-coercive
- **Study Instruments/Interventions:** safe, justifiable, respectful
- **Risk Management:** potential benefits outweigh risks, risks are distributed equitably across participants, participants ultimately make decisions about risk acceptability, participants are not left to seek relevant resources and supports on their own

# Operationalizing TCPS2 in Research Projects

- **Data Management:** participant privacy and confidentiality; stewardship of participant's information; respects participant's data rights; complies with federal, provincial, and institutional privacy regulations
- **Compensation**: non-coercive, respects right to withdraw without penalty
- **Dissemination**: efforts made to communicate results to all interested and participating parties and not just to academics, privacy/confidentiality is respected in dissemination
- **RELATIONSHIPS:** potentially impacted parties are invited to meaningfully contribute to the design, execution, and dissemination of the project; the needs of the research team (e.g. timeline pressures) are not put ahead of the needs of individuals or groups impacted by the project

# TCPS2

## Pros

- Provides common framework across Canada
- Revised multiple times since its introduction in 1998 based on feedback
- Aligns with many people's intuitions about the role of free and informed consent in determining what is morally permissible

## Cons

- Built upon an ethical framework (Anglo-American "Analytic" Philosophy) widely acknowledged to have excluded voices of women, racialized peoples, 2SLGBTQ2+ peoples, Indigenous peoples and many others.
- It may sometimes prioritize:
  - Rules over relationships
  - Individual over community
  - Human systems over non-human systems (e.g., ecosystems)

# TCPS2 – Chapter 9

Research Involving

the First Nations, Inuit, and Métis Peoples of Canada

# TCPS2 - Chapter 9
# Research Involving the First Nations, Inuit and Métis Peoples of Canada

"This chapter is designed to serve as a framework for the ethical conduct of research involving Indigenous peoples. It is offered in a spirit of respect.

It is **not intended to override or replace ethical guidance offered by Indigenous peoples themselves**.

Its purpose is to ensure, to the extent possible, that research involving Indigenous peoples is **premised on respectful relationships**. …

**Building reciprocal, trusting relationships will take time**. This chapter provides guidance, but it **will require revision** as it is implemented"

# TCPS2-2022: Chapter 9
# Considerations for Indigenous Engagement

"The conditions under which engagement is required **include, *but are not limited to***:

a) research conducted on First Nations, Inuit or Métis **lands**;
b) **recruitment criteria** that **include Indigenous identity** as a factor for the entire study or for a subgroup in the study;
c) research that seeks input from participants regarding a community's **cultural heritage, artefacts, traditional knowledge or unique characteristics**;
d) research in which **Indigenous identity or membership** in an Indigenous community is **used as a variable for the purpose of analysis of the research data**; and
e) **interpretation** of research **results** that will **refer to Indigenous communities, peoples, language, history or culture**.

# Indigenous Self-Governance and Relational Ethics

**Indigenous relationship-based moral codes help ensure responsible and respectful research:**

- "This includes the reciprocal nature of our relationships, my responsibility to uphold and respect my fellow community member's free will and agency to make choices that are best for them, and my accountability to them to strive for no harm, which existed prior to the research and will continue throughout the research process and beyond." (John, 2024, p. 11)
- "… This would not give Indigenous researchers a free pass on research ethics with Indigenous communities. Indeed, our accountability is greater. Breaking trust is the worst thing that could happen: it brings shame to our family names, it ends the work with the community and word spreads between communities. For someone like me, whose research is rooted entirely in service to Indigenous Peoples, with no separation between the personal and professional, that would be devastating." (Grenz, 2023, 221)

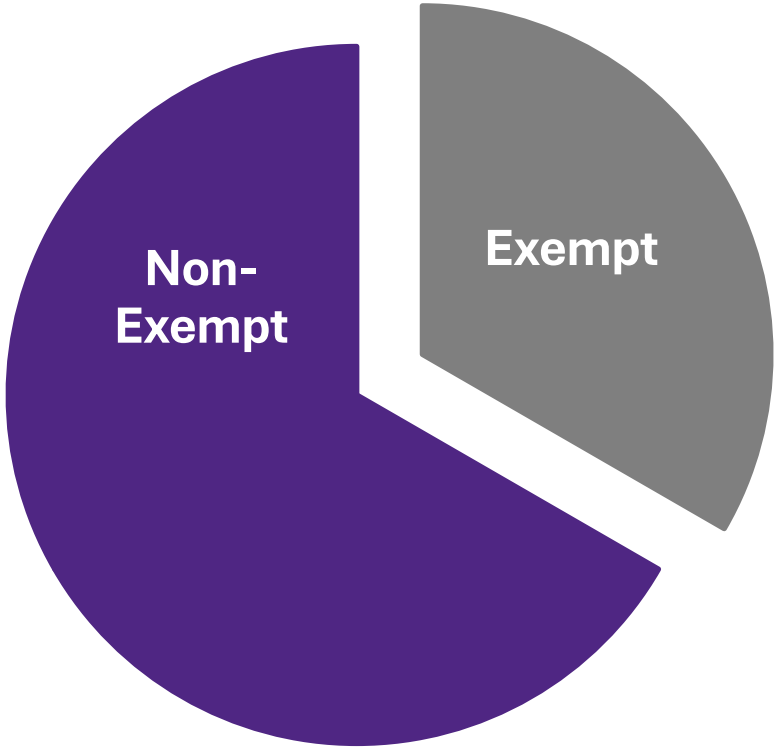
TCPS2 may conflict with Indigenous traditions and protocols and so careful consultation will be necessary to ensure Indigenous ways are respected and upheld.

# TCPS2 Exempt Activities: Do I need REB approval?

# TCSP2's Two-Step Approach to Defining what activities require REB oversight

**Step 1: Define Research Involving Human Participants**


**Step 2: Outline Exemptions**



# What counts as "research" for the purposes of Research Ethics?

**Research** =
an undertaking
intended to **extend knowledge**
through a
**disciplined inquiry or systematic investigation**
**…**
with the expectation that the method, results, and conclusions **will be able to withstand the scrutiny of the relevant research community."**

(TCPS2-2022, Glossary "Research", and Chapter 1A)

# What counts as "human participant" for the purposes of Research Ethics?

**Participant** =

**an individual**

**whose data, biological materials, or responses**

to interventions, stimuli, or questions

by a researcher

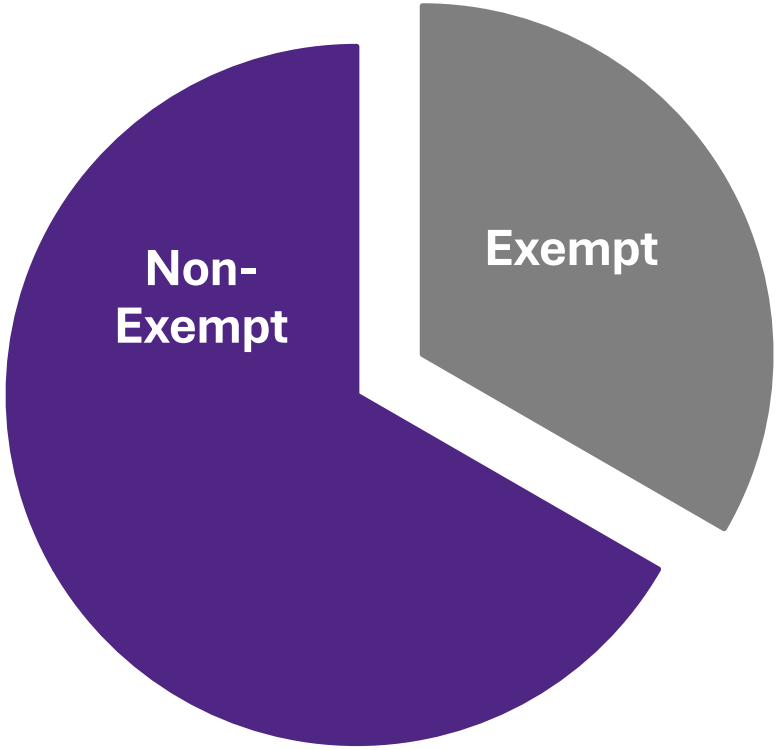
are **relevant to answering the research question**(s)

(TCPS2, Article 2.1)

# TCSP2's Two-Step Approach to Defining what activities require REB oversight

**Step 1: Define Research Involving Human Participants**


**Step 2: Outline Exemptions**



# TCPS2-2022, Article 2.2
## Publicly Available Information

"Research does not require REB review when it relies **exclusively** on information that is:

a. **publicly available** through a **mechanism** set out by **legislation** or **regulation** and that is **protected by law**; or

b. in the **public domain** and the individuals to whom the information refers have **no reasonable expectation of privacy**."

# TCPS2-2022, Article 2.3
# **Naturalistic Observational Research**

"REB review is not required for research involving the **observation** of people in **public places** where:

a. it does **not** involve any **intervention** staged by the researcher, or **direct interaction** with the individuals or groups;

b. individuals or groups targeted for observation have **no reasonable expectation of privacy**; and

c. any dissemination of research results **does not allow identification of specific individuals**."

# TCPS2-2022, Article 2.4
## Secondary use of anonymous information

"REB review is not required for research that relies **exclusively** on **secondary use** of **anonymous** information, or **anonymous** human biological materials, **so long as** the process of data linkage or recording or dissemination of results **does not generate identifiable information**. …

**Secondary use** refers to the use in research of information or human biological materials **originally collected for a purpose other than the current research purpose**.

Anonymous information and human biological materials are **distinct from** those that have been **coded**, and also from those that have been **anonymized** (Section A of Chapters 5 and 12)."

# Key Terminology for Article 2.4: TCPS-2022, 5A, "Types of Information"

| Exempt: Anonymous | Non-Exempt: Deidentified, Coded, Anonymized |
|---|---|
| **"Anonymous information** - the information **never** had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low." | **"Coded information** – direct identifiers are **removed** from the information and **replaced with a code**. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual names so data can be re-linked if necessary).<br><br>**Anonymized information** – the information is **irrevocably stripped** of direct identifiers, a **code is not kept** to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low." |

# TCPS2-2022, Article 2.5
## Quality Assurance/Quality Improvement/ Program Evaluation Activities (QA/QI/PE)

"Quality assurance and quality improvement studies, program evaluation [QA/QI/PE] activities, and performance reviews, or testing within normal educational requirements when **used exclusively for assessment, management or improvement purposes**, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review."

*For more information, please see the Office of Human Research Ethics' guidance document entitled: "Distinguishing Between Quality Assurance/Improvement & Research" available at:*
*https://uwo.ca/research/_docs/ethics/hsreb_guidelines/Distinguishing_Between_QA_QI_PE_Research-9Mar2021_Updated.pdf*

# TCPS2-2022, Article 2.6
# **Creative Practice**

"Creative practice is a process through which **an artist makes or interprets a work or works of art**.

It may also include **a study of the process of how a work of art is generated**."

# TCPS2-2022:
# Summary of Exemptions from REB Oversight

1) Publicly available information (see TCPS2 Article 2.2),
2) Naturalistic observational research (see TCPS2 Article 2.3),
3) Secondary use of anonymous information (see TCPS2 Article 2.4),
4) Quality Assurance/Quality Improvement/Program Evaluation Activities (see TCPS2 Article 2.5),
5) Creative Practice (see TCPS2 Article 2.6).

# TCPS2 in Action: Western's Research Ethics Boards

Western

# TCPS2 Governance Requirements for REB's

Governance requirements outlined in Chapter 6 of TCPS2-2022.

**REB Mandate According to TCPS2**:

"The institution shall grant the REB the mandate to **review the ethical acceptability of research on behalf of the institution**, including **approving**, **rejecting**, **proposing modifications** to, or **terminating** any **proposed** or **ongoing** research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the institution, using the considerations set forth in this Policy." (Article 6.3)

# Western's Research Ethics Boards

| Non-Medical Research Ethics Board (NMREB) | Health Sciences Research Ethics Board |
|---|---|
| • Social Sciences and Humanities approaches and methodologies to research involving humans<br>• Example borderline areas: mental health/illness; use of imaging technology (MRI, fMRI), ethnography in clinical settings, etc. | • Medical interventions, medical settings (e.g., hospital, clinic, etc.), medical techniques, medical devices<br>• Participants include, patients, health care professional, caregivers<br>• Involves movement or exertion beyond normal daily activities (e.g. kinesiology studies)<br>• Results will have implications for medicine/health care fields and/or will be published in a medical journal. |

**What Board do I use?:** https://uwo.ca/research/ethics/human/Resources/which_reb.html

# TCPS2 Governance Requirements for REB's

"The REB shall consist of at least five members, including both men and women, of whom **at least**:

a) two members have **expertise** in relevant **research disciplines, fields and methodologies** covered by the REB;
b) one member is **knowledgeable in ethics**;
c) one member is **knowledgeable in the relevant law**. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
d) one **community member** has **no affiliation with the institution**.

It is advisable that each member be appointed to formally fulfill the requirements of only one of the above categories.
To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB."
*(TCPS2-2022, Article 6.4)*

Lists of Western's REB members area available at:
https://uwo.ca/research/ethics/human/about/administrative_information.html

# TCPS2-2022: Two Types Review Article 6.12

| Full Board Review (Default) | Delegated Review |
| --- | --- |
| • Assigned to a Full Board Meeting (NMREB monthly; HSREB every 2 weeks)<br>• Reviewed by all REB members scheduled to attend that meeting | • Assigned to a Board Member and an Ethics Officer for review (reviewed on first-come-first-serve basis) |

# TCPS2-2022: Criteria for Delegated Review

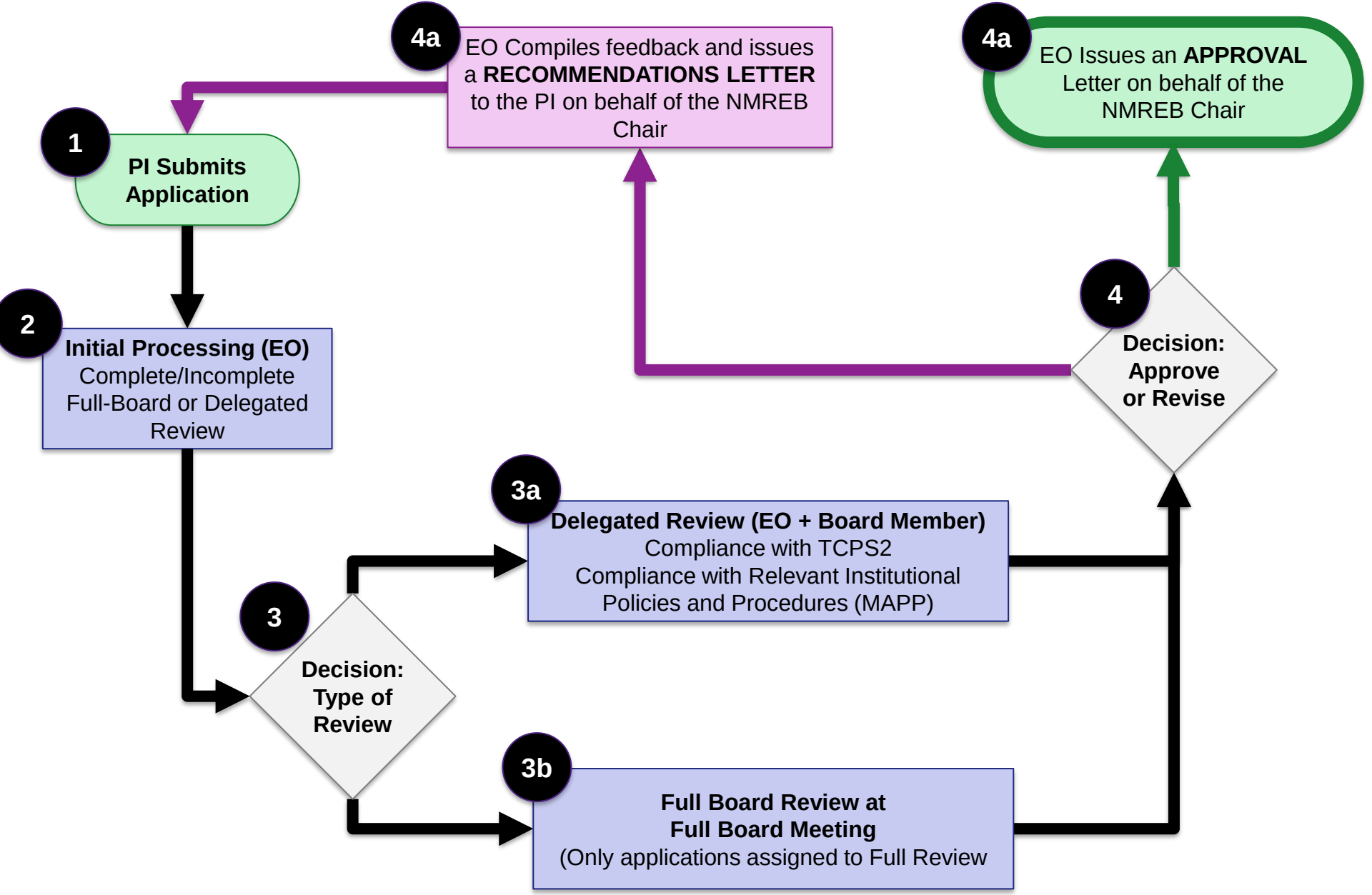
TCPS2-2022 criteria to be eligible for delegated review: the research is “minimal risk” (Article 6.22)

“For the purposes of this Policy, **"minimal risk" research is defined as research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.**

In their assessment of the acceptable threshold of minimal risk, **REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis.** Their inclusion in research should not exacerbate their vulnerability” (Ch. 2b)

# REB Review Process

Full Board & Delegated


4a
EO Compiles feedback and issues a **RECOMMENDATIONS LETTER** to the PI on behalf of the NMREB Chair
4a
EO Issues an **APPROVAL** Letter on behalf of the NMREB Chair
1
**PI Submits Application**
2
**Initial Processing (EO)**
Complete/Incomplete
Full-Board or Delegated Review
4
**Decision: Approve or Revise**
3a
**Delegated Review (EO + Board Member)**
Compliance with TCPS2
Compliance with Relevant Institutional Policies and Procedures (MAPP)
3
**Decision: Type of Review**
3b
**Full Board Review at Full Board Meeting**
(Only applications assigned to Full Review

# Timelines for Initial Review of Delegated Applications (NMREB)

- **Initial Submissions**: Recommendations are to be provided to applicants **within 3-4 weeks** (depending on volume)

- **Amendments**: Reviewed **within two weeks** (depending on volume

# Estimating timeline to approval for applications to the NMREB

| Action | Agent | Duration |
|---|---|---|
| Initial NMREB Recommendations | NMREB | 3-4 weeks |
| Applicant Response to Recommendations | Applicant | 1-2 weeks* |
| NMREB Approval Based on Response to Recommendations ** | NMREB | 1-2 weeks |

**Total: ~4-8 weeks**

**Notes:**

*The time estimated for applicant response is based on the 2023 average of 12 days.

**In some cases, the application cannot be approved because the applicant's response to the initial recommendations requires additional follow-up recommendations (e.g., recommendations were missed, changes indicated were not actually made, new information raises new concerns, etc.). If this occurs, follow-up recommendations are sent and applicants must provide a new response. This adds the time needed for the applicant to respond to follow up recommendations (1-2 weeks) and for the NMREB to review the response to follow-up recommendations (1-2 weeks).

# TCPS2 in Action:
# Office of Human Research Ethics (OHRE)
# Supporting the REB and Applicants

Western

# Office of Human Research Ethics Western Research

- **WREM System: Submit REB Applications:**
  - https://applywesternrem.uwo.ca/
- **Non-Medical Research Ethics Board (Peer-Review)**
- **Guidelines and Template**
  - https://uwo.ca/research/ethics/human/board_guidelines.html

# Guidance Documents

- https://uwo.ca/research/ethics/human/board_guidelines.html
- Highlighted Guidance Documents:
  - NMREB Consent Form Guidance Document
  - Participant Recruitment
  - Guidelines for Incentives, Reimbursement and, Compensation
  - Data Security and Confidentiality
  - Multi-Jurisdictional Research Guidance
  - Distinguishing Between Quality Assurance/Improvement & Research
  - Student Research and Pedagogical Activities
  - Ethical Challenges in Online Research: Bots, suspicious data and other issues

# Human Research Ethics Chairs & Staff

**Chairs**

- **Dr. Naveen Poonai**, Chair, Health Sciences (HS) REB, npoonai2@uwo.ca
- **Dr. Roberta Berard**, Vice-Chair, Health Sciences (HS) REB, rberard2@uwo.ca
- **Dr. Emma Duerden**, Vice-Chair, Health Sciences (HS) REB, eduerden@uwo.ca
- **Dr. Isha DeCoito**, Chair, Non-Medical (NM) REB, idecoito@uwo.ca
- **Dr. Riley Hinson**, Vice-Chair, Non-Medical (NM) REB, hinson@uwo.ca

**Director**

- **Erika Basile**, Director, Research Ethics & Compliance, 519-661-2111, ext. 86764, ebasile@uwo.ca

**Administrative Staff**

- **Nicole Holme**, Administrative Assistant, 519-661-2111, ext. 84691, nicole.holme@uwo.ca

**Ethics Staff**

- **Trevor Bieber**, Non-Medical Ethics Officer, 519-661-2111, ext. 84301, tbieber2@uwo.ca
- **Grace Millet,** Non-Medical Ethics Officer, 519-661-2111, ext. 85501, gmillet@uwo.ca
- **Jhananiee Subendran**, Health Sciences Ethics Officer, 519-661-2111, ext. 86811, jsubendr@uwo.ca
- **Joshua Hatherley**, Ethics Coordinator,
- **Katelyn Harris**, Non-Medical Ethics Officer, *On Leave*
- **Kelly Patterson**, Non-Medical Ethics Officer, 519-661-2111, ext. 82256, kpatte32@uwo.ca
- **Melanie Munroe**, Health Science Ethics Officer, 519-661-2111, ext. 87746, mmunro54@uwo.ca
- **Nicola Geoghegan-Morphet**, Health Sciences Ethics Officer, 519-661-2111, ext.84793,ngeoghe@uwo.ca
- **Patricia Sargeant**, Health Sciences Ethics Officer, 519-661-2111, ext. 85990, psargean@uwo.ca

# Submitting to Western's REBs:

# Application Forms:
# Western's Research Ethics Management System (WREM)

# Post-Approval Forms ("Sub-Forms" in WREM)

**Initial Application Form**

| | |
|---|---|
| Amendment | • Modifications to the approved application and/or study documents.<br>• Amendments must be approved by the REB prior to implementation. |
| Reportable Event | • Protocol Violation/Deviation (unapproved study activities)<br>• Serious Adverse Event (harmful outcome to participant(s))<br>• FYI (minor updates to REB)<br>• Participant Complaints/Privacy Breaches (contact REB prior to submission)<br>• Data Safety Monitoring Board/Committee Reports |
| Continuing Ethics Review (CER) | • Annual update required for studies extending beyond one year (TCPS2-2022, Article 6.14)<br>• 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 records). |

# NMREB Initial Application Form

| Section | Questions |
|---|---|
| Section 1 - General Information | 1.1 - 1.13 |
| Section 2 - Study Description | 2.1 - 2.19 |
| Section 4 - Recruitment Process | 4.1 |
| Section 5 - Consent Process | 5.1 - 5.6 |
| Section 6 - Risks, Benefits, and Safety | 6.1 - 6.5 |
| Section 7 - Confidentiality and Data Security: Description of Study Records | 7.1 - 7.6 |
| Section 8 - Confidentiality and Data Security: Transfer/Transport of Study Records | 8.1 - 8.3 |
| Section 9 - Confidentiality and Data Security: Storage, Retention and Destruction of Study Records | 9.1 - 9.6 |
| Section 10 - Compensation | 10.1 - 10.2 |
| Section 11 - Translation | 11.1 - 11.5 |
| Section 12 - Funding | 12.1 - 12.3 |
| Section 13 - Conflict of Interest (actual, apparent, perceived, or potential) | 13.1 - 13.7 |
| Section 15 - Confirmation of Responsibility | 15.1-15.2 |


Western

UNIVERSITY · CANADA