

Faculty of Education

Research Ethics Overview

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Plan

- 1) **Why is research ethics required? (~5 m)**
- 2) **Research Ethics in Canada: TCPS2-2022 (~10m)**
- 3) **Do I need to submit? Exempt and Non-Exempt Activities Under TCSP2 (~10m)**
- 4) **Research Involving Indigenous People (TCPS2, Ch. 9) (~10m)**
- 5) **Western's REBs (~5m)**
- 6) **Office of Human Research Ethics (OHRE): Supporting REBs and Applicants (~5m)**
- 7) **Submitting to the REB: Application Forms in WREM (~5m)**

Why do Governments, Impose Research Ethics Requirements?

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

Research Ethics Atrocities

CANADA

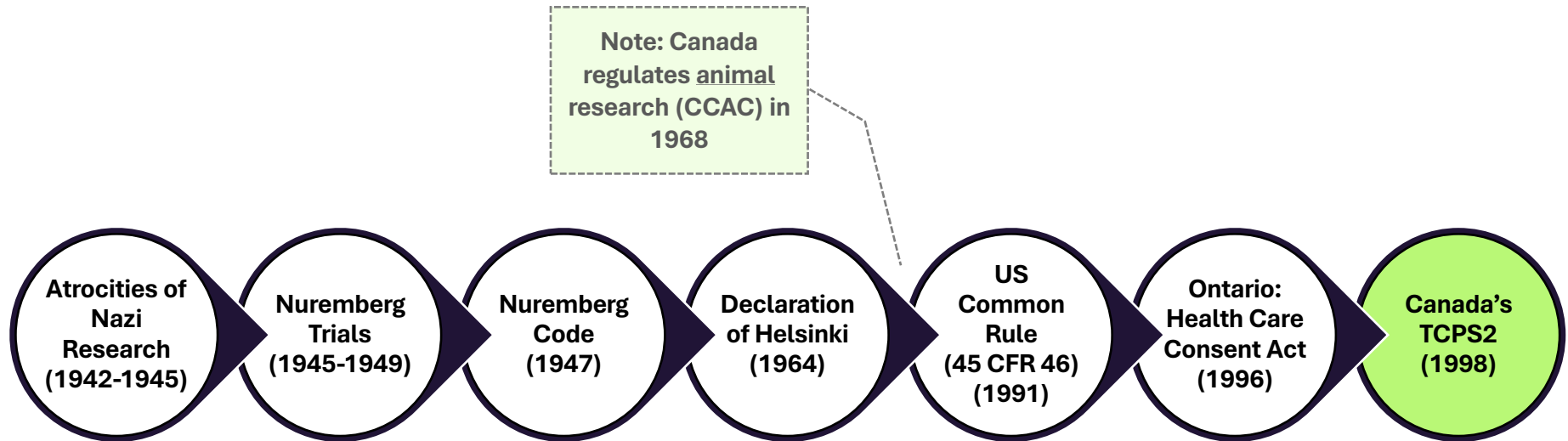
Truth and Reconciliation Commission: Final Report, Volume 1 – Part 2.

- 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

Other Examples of 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)

Historical Development of Some Human Ethics Regulations



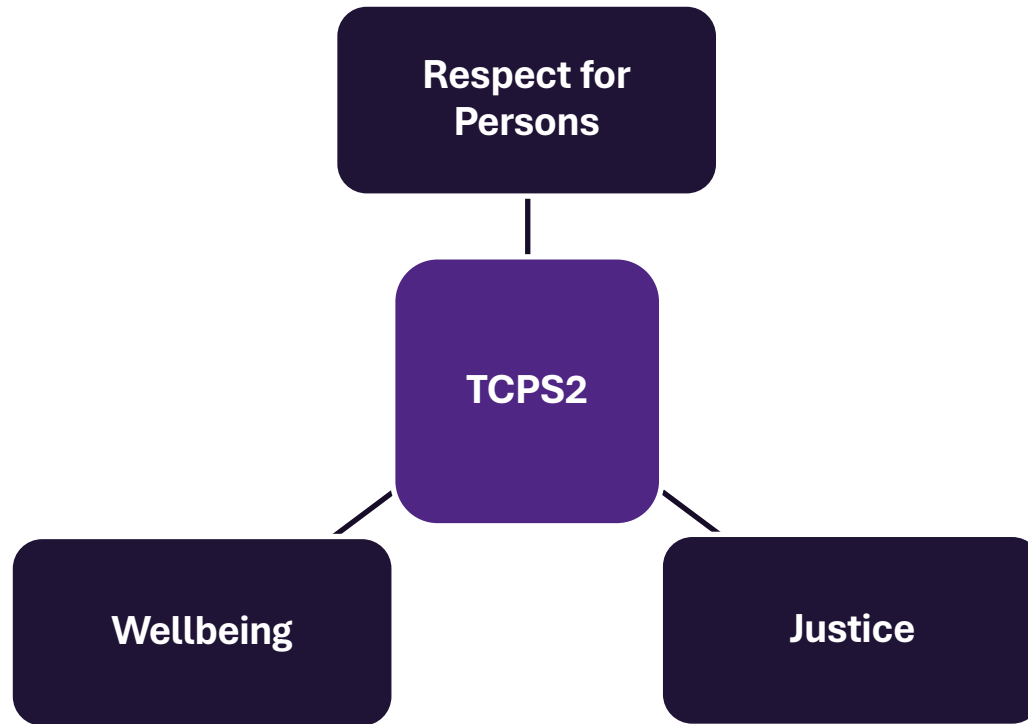
Research Ethics in Canada: TCPS2-2022: Core Principles

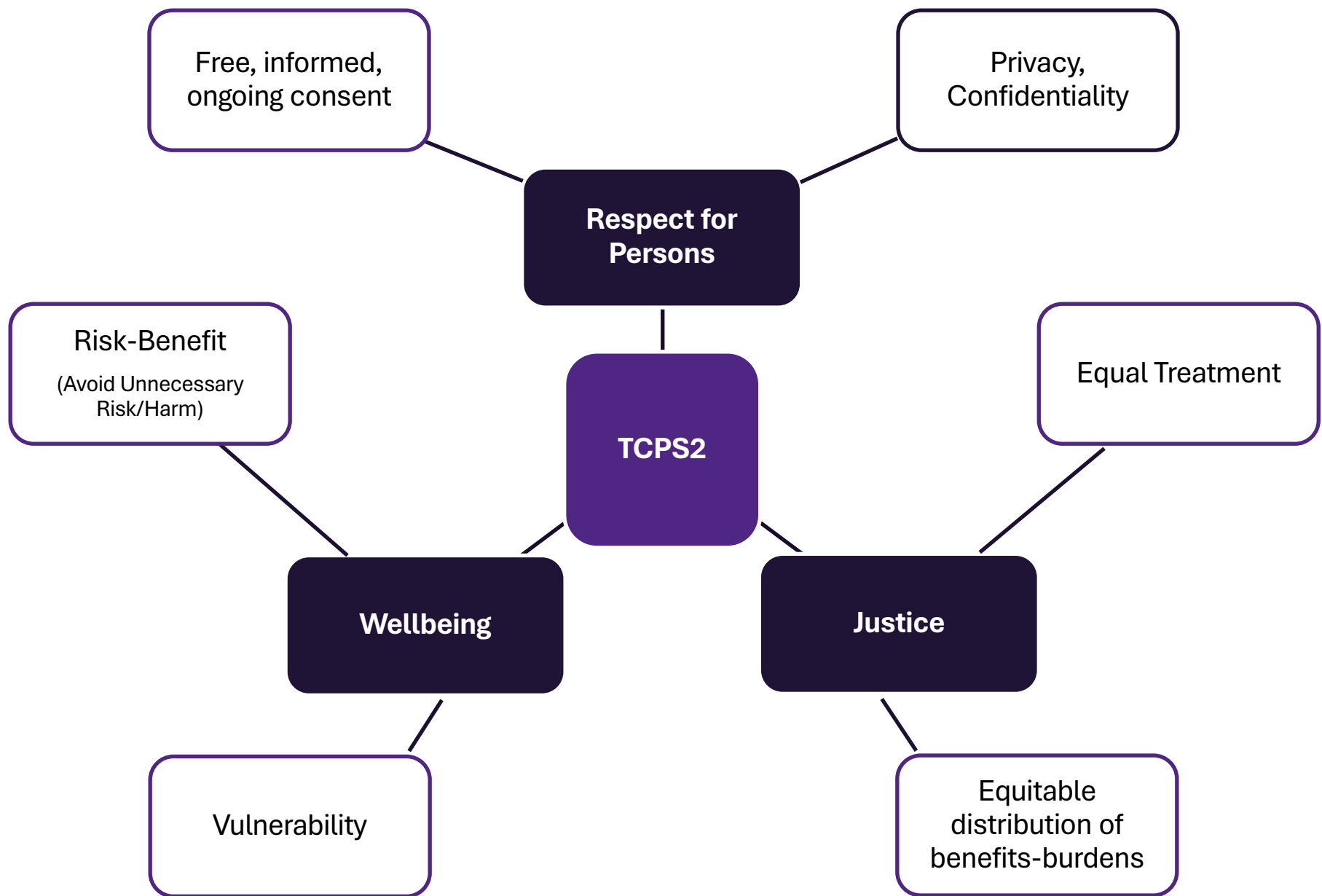
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS 2 (2022)

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

TCPS2:

Three Core Principles





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

Research Ethics in Canada: Do I need REB approval?

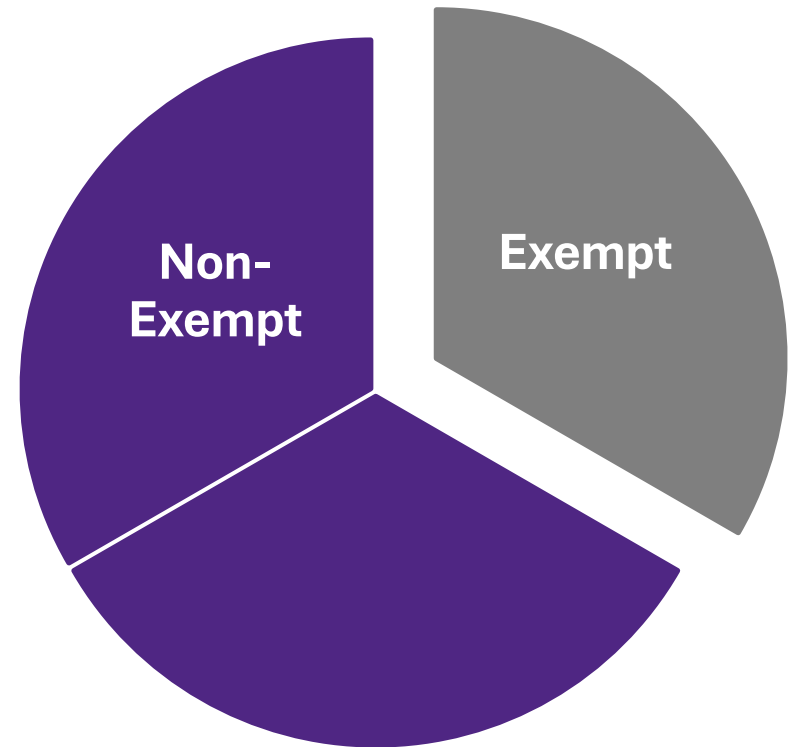
TCPS2 *Exempt* Activities

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)

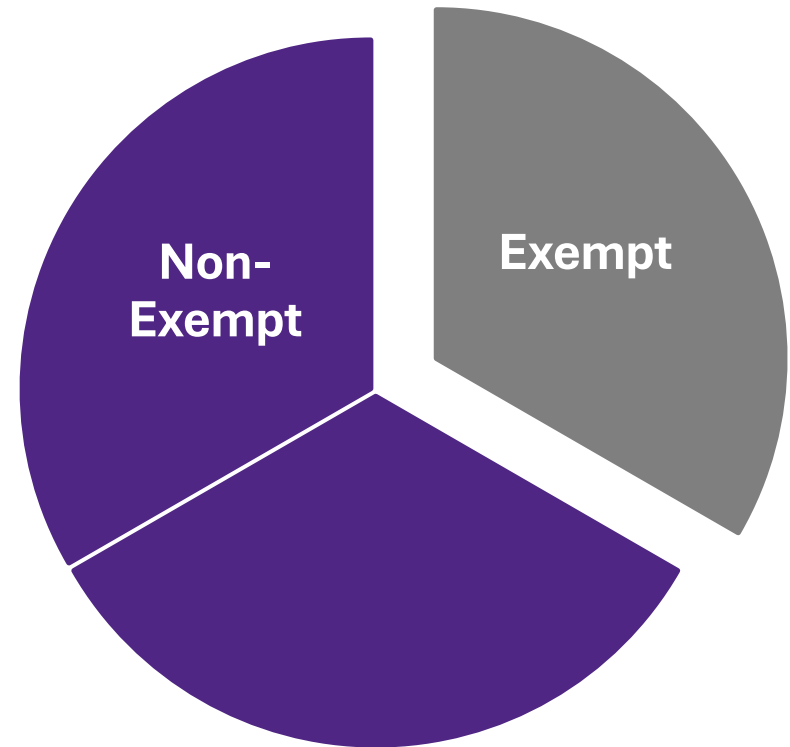
(TCPS2, Article 2.1)

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

Step 1: Define Research Involving Human Participants



Step 2: Outline Exemptions



Exemption #1: 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**.”

Exemption #2: 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.**”

Exemption #3: 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

“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.”

Non-Exempt: Deidentified, Coded, Anonymized

“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).

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.”

Exemption #4: 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://www.uwo.ca/research/doc/compliance/human_ethics/guidelines_templates/Distinguishing_Between_QA_QI_PE_Research-9Mar2021_Updated.pdf

Exemption # 5: 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**.

However, research that ***employs creative practice*** to **obtain responses** from participants that will be analyzed to answer a research question is subject to REB review.”

Summary of TCPS2's 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 and Chapter 5A, “Types of Information”),
- 4) Quality Assurance/Quality Improvement/Program Evaluation Activities (see TCPS2 Article 2.5),
- 5) Creative Practice (see TCPS2 Article 2.6).

TCPS2-2022, Chapter 9: “Research Involving the First Nations, Inuit and Métis Peoples of Canada”

TCPS2-2022: Chapter 9

Indigenous Engagement

“Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community.

TCPS2-2022: Chapter 9

Indigenous Engagement

“Nothing about us, without us.”

**Always research with or by Indigenous people,
never research on Indigenous people.**

Indigenous “Community”

TCPS2-2022, Ch. 9A: Key Concepts and Definitions

- According to TCPS2, a Community is defined as: “a group of people with a **shared identity or interest** that has the **capacity** to **act** or **express itself as a collective.**”
- TCPS2 recognizes **three kinds** of ‘communities’:
 - 1) Territorial Communities
 - 2) Organizational Communities
 - 3) Communities of Interest

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.

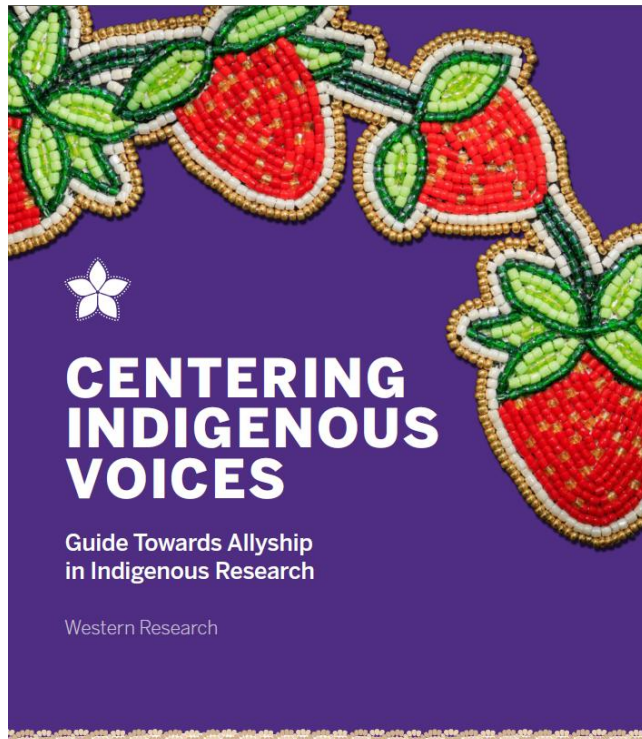
It is **not intended to override or replace ethical guidance offered by Indigenous peoples themselves.**

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”

Resources

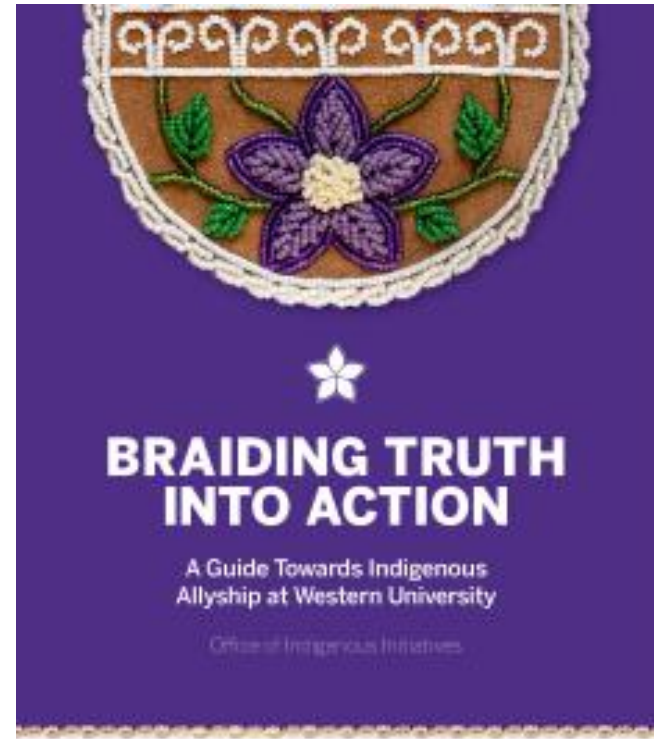
Centering Indigenous Voices: Guide Towards Allyship in Indigenous Research



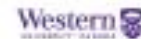
JULY 2025



Braiding Truth into Action: A Guide Towards Indigenous Allyship at Western University



AUGUST 2025



Applying for Ethics at Western: Western's Research Ethics Boards

Western's Research Ethics Boards

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

What Board do I use?: <https://www.uwo.ca/research/compliance/human-research-ethics/which-board.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) - Reviewed by all REB members scheduled to attend that meeting	Assigned to a Board Member and an Ethics Specialist for review (reviewed on first-come-first-serve basis)

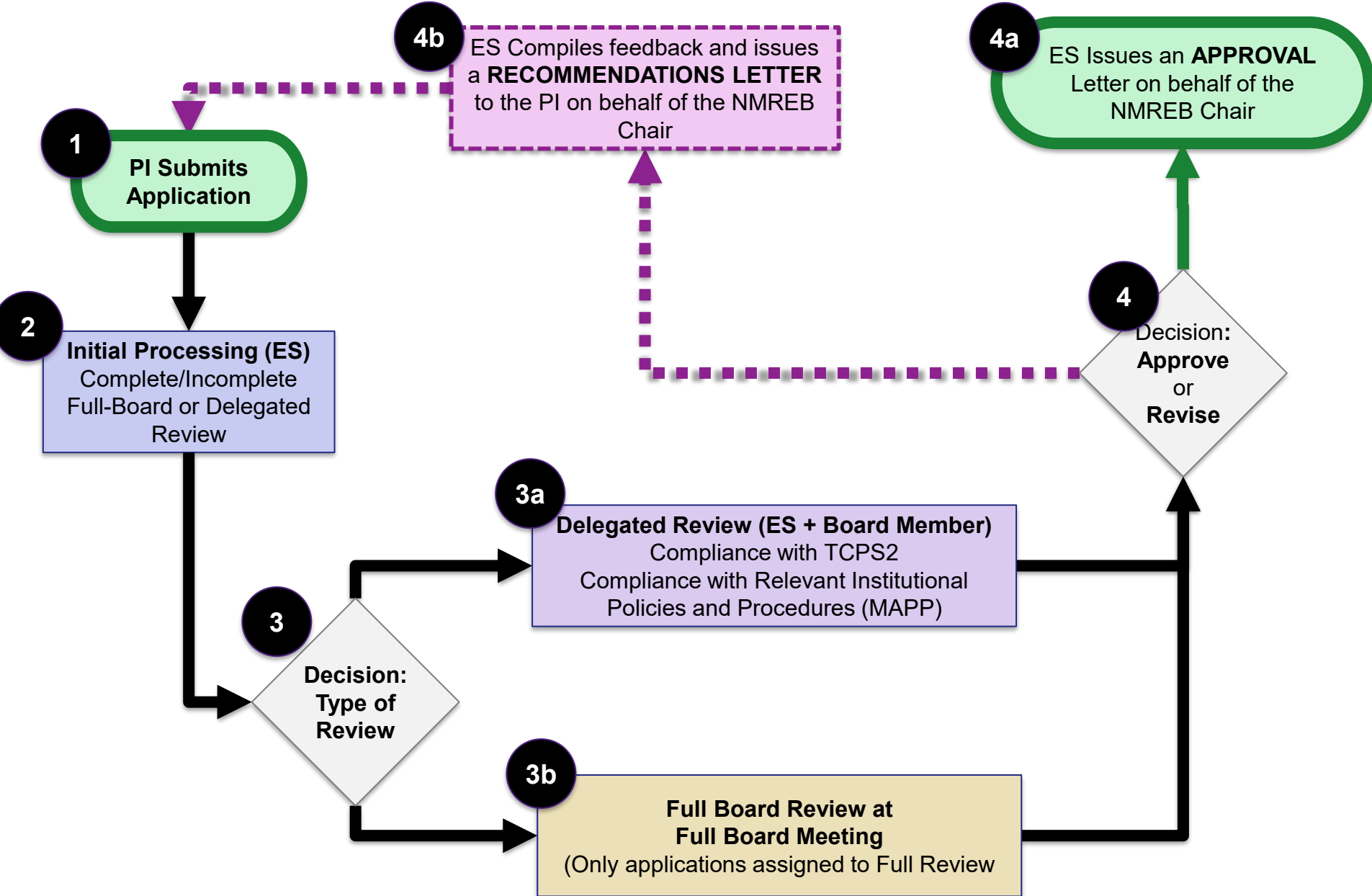
TCPS2-2022: Criteria for Delegated Review: “Minimal Risk”

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)

Applying for Ethics at Western: REB Review Process Full Board & Delegated



Timelines for Initial Review of Delegated Applications (NMREB)

- **Initial Submissions:** Recommendations are to be provided to applicants **within 2-4 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).

Applying for Ethics at Western: Office of Human Research Ethics (OHRE) Supporting the REB and Applicants

Office of Human Research Ethics Western Research

- The OHRE supports **both** 1) the **REBs**, and 2) **researchers** through supports such as:
 - **WREM System: Submit REB Applications:**
 - <https://applywesternrem.uwo.ca/>
 - **Non-Medical Research Ethics Board (Peer-Review)**
 - **Guidelines and Template**
 - <https://uwo.ca/research/compliance/human-research-ethics/index.html>

Guidance Documents

- **All guidance documents available at:**
- <https://www.uwo.ca/research/support/resources/human-ethics/guidelines-templates.html>
- **Highlighted Guidance Documents:**
 - NMREB Consent Form Guidance Document
 - Participant Recruitment
 - Guidelines for Incentives, Reimbursement and, Compensation
 - Data Security and Confidentiality
 - 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
- **Dr. Emma Duerden**, Vice-Chair, Health Sciences (HS) REB
- **Dr. Christopher Hansebout**, Vice-Chair, Health Sciences (HS) REB

- **Dr. Jayne Garland**, Chair, Non-Medical (NM) REB
- **Dr. Riley Hinson**, Vice-Chair, Non-Medical (NM) REB

Director

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

Administrative Staff

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

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- **Trevor Bieber**, Non-Medical Ethics Specialist, 519-661-2111, ext. 84301, tbieber2@uwo.ca
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- **Jhananiee Subendran**, Health Sciences Ethics Specialist, 519-661-2111, ext. 86811, jsubendr@uwo.ca
- **Katelyn Harris** (on secondment), Non-Medical Ethics Specialist, 519-661-2111 (84768), katelyn.harris@uwo.ca
- **Kelly Patterson**, Non-Medical Ethics Specialist, 519-661-2111, ext. 82256, kpatte32@uwo.ca
- **Nicola Geoghegan-Morphet**, Health Sciences Ethics Specialist, 519-661-2111, ext. 84793, ngeoghe@uwo.ca
- **Elizaveta Shpilevaia**, Health Sciences Ethics Specialist, ext. 86563, eshpilev@uwo.ca

Submitting to Western's REBs:

Application Forms:

**Western's Research Ethics
Management System (WREM)**

Getting Set Up in WREM

- 1) **Complete TCPS2-CORE online training** (~4 hours): <https://tcps2core.ca/welcome>
- 2) **Request a WREM Account** (“New User” at <https://applywesternrem.uwo.ca/> - 1-3 business days)
- 3) **Login to WREM and start a new “Project” (Application)**

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

WREM Forms and “Sub-Forms” in WREM

Initial Application Form

Amendment

- Modifications to the approved application and/or study documents.
- Amendments must be approved by the REB prior to implementation.

Reportable Event

- Protocol Violation/Deviation (unapproved study activities)
- Serious Adverse Event (harmful outcome to participant(s))
- FYI (minor updates to REB)
- Participant Complaints/Privacy Breaches (contact REB prior to submission)
- Data Safety Monitoring Board/Committee Reports

Continuing Ethics Review (CER)

- Annual update required for studies extending beyond one year (TCPS2-2022, Article 6.14)
- 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).