School of Epidemiology and Public Health
The University of Ottawa
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The Ethics of Research Involving Humans based on the TCPS

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PANEL ON RESEARCH ETHICS
Navigating the ethics of human research

Outline

1. Introduction
    a. What is the Secretariat on Responsible Conduct of Research?
    b. What is the TCPS?
    c. Does the TCPS apply to your research?
    d. Is research ethics board review required for your research?
2. Ethics issues and considerations relevant to research involving communities
    a. Consent
    b. Fairness and equity in research participation
    c. Privacy and confidentiality

1. Introduction

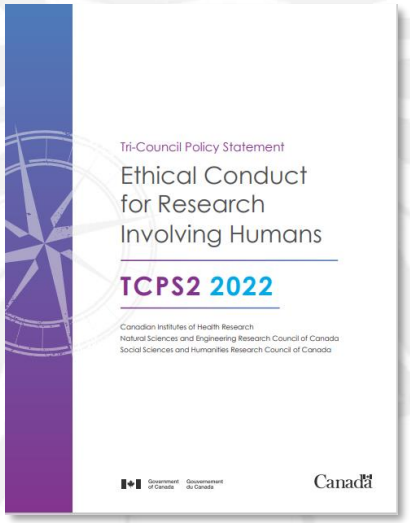
1a. What is the Secretariat on Responsible Conduct of Research?

Created by CIHR, NSERC and SSHRC with a dual mandate:

A. Ethics of human research
   - Panel on Research Ethics (PRE)
   - *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* – TCPS (2022)

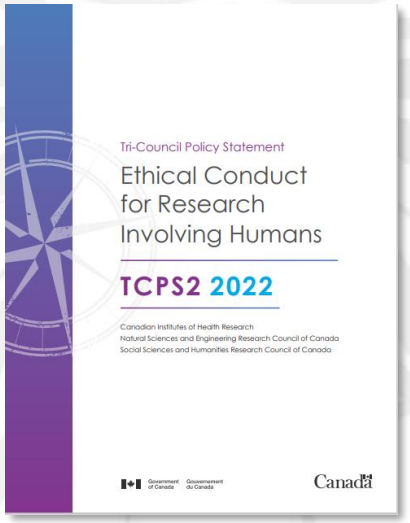
B. Responsible conduct of research
   - Panel on Responsible Conduct of Research (PRCR)
   - *Tri-Agency Framework: Responsible Conduct of Research* – RCR Framework (2021)

1b. What is the TCPS? (1/3)



- *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)
- Tri-Council: CIHR, NSERC and SSHRC
- Covers all fields of research involving humans (Health, Natural Sciences and Engineering, Social Sciences and Humanities)
- Updated in 2010, 2014, 2018, 2022
- Implementation of TCPS is an institutional responsibility

1b. What is the TCPS? (2/3)



1. Ethics Framework
2. Scope and Approach
3. The Consent Process
4. Fairness and Equity in Research Participation
5. Privacy and Confidentiality
6. Governance of Research Ethics Review
7. Conflicts of Interest
8. Multi-jurisdictional Research

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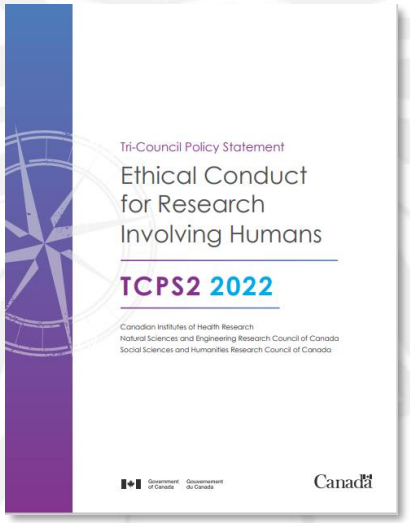
9. Research involving First Nations, Inuit, and Métis Peoples of Canada
10. Qualitative research
11. Clinical Trials
12. Human Biological Materials + Materials Related to Human Reproduction
13. Human Genetic Research

1b. What is the TCPS? (3/3)



Core Principles

– **Respect for Persons**: respecting a person's judgment and freedom to choose without interference

– **Concern for Welfare**: considering the quality of life of a person (e.g. physical, economic, social) with a view to protecting participants' welfare

– **Justice**: treating people fairly and equitably

1c. Does the TCPS apply to you? (1/2)

- Are you affiliated with an institution eligible to receive research funding from one of the three federal research funding Agencies?
- Are you conducting “research” that involves “humans” as defined in the TCPS?
  - “**Research**” is an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation
  - “**Human participants**” are those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question

1c. Does the TCPS apply to you? (2/2)

TCPS definitions relevant to PPH-epidemiology

- **Epidemiological observational research**: An epidemiological study that does not involve any intervention by the researcher. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to changes in other characteristics.
- **Epidemiology**: The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.

1d. Is REB review required for your research? (1/2)

- **Activities not requiring REB review:**
  - Activities that are not research (e.g., quality assurance, quality improvement, program evaluation, creative practice) (Art. 2.5, 2.6)

- **Research exempt from REB review under certain conditions:**
  - Publicly available and protected by law (Art. 2.2a)
  - Publicly accessible with no expectation of privacy (Art. 2.2b)
  - Observation in public places (subject to conditions) (Art. 2.3)
    - Clarification related to epidemiological observational research
  - Secondary use of anonymous info/HBM (Art. 2.4)

Is REB review required for the secondary use of datasets containing personal information such as those that Statistics Canada maintains? (1/2)

- Research that relies exclusively on information that is "publicly available through a mechanism set out by legislation or regulation and that is protected by law" does not require REB review.
- Exemption is "based on the presence of a custodian/steward designated in accordance with access to information and privacy legislation who protects privacy and proprietary interests associated with the information (e.g., an access to information and privacy coordinator or a guardian of Canadian census data)" (Application of Art. 2.2).
- Statistics Canada files are an example of this type of information.

Is REB review required for the secondary use of datasets containing personal information such as those that Statistics Canada maintains? (2/2)

- Data linkage of different sources of information could give rise to new forms of identifiable information that would raise issues of privacy and confidentiality when used in research and would therefore require REB review (Article 5.7).
- Researchers must satisfy the REB that:
  - Data linkage is essential to the research; and
  - Appropriate security measures will be implemented to safeguard information.
- The goal is to assess and minimize risks of re-identification.
- Legislation and organizational policies may regulate data linkage in specific circumstances.

1d. Is REB review required for your research? (2/2)

- Public surveillance: e.g. in support of a public health program or under the jurisdiction of a public health authority without a research goal – does not fall within the TCPS definition of research and does not require REB review.
  - E.g., public health wastewater surveillance during the pandemic.

2. Ethics issues and considerations relevant to research involving communities

2a. Consent (1/4)

- Consent process comprises three principles (Art. 3.1- 3.3):
  - Voluntary - informed - ongoing
- Must precede collection of, or access to research data (Art. 3.5)
- Different modalities of seeking consent, but must be documented (Art. 3.12)
- Alterations to consent requirements : Exceptions to the requirement to seek prior consent, requirement for debriefing (Art. 3.7 A&B)

2a. Consent (2/4)

Special consent considerations in research involving communities

- Some PPH cannot be done with prior informed consent. Examples:
  - A cluster-randomized trial comparing two different stop smoking campaigns in two or more communities.
  - A study comparing different types of water treatment facilities.

2a. Consent (3/4)

Special consent considerations in research involving communities

- Researchers should seek community engagement prior to data collection.
- Onus is on researchers to inform their REB of the need for the alteration/exception.
- REBs should have PPH expertise involved in reviews of this type of research.

Scenario # 1 – Exceptions to the requirement to seek prior consent

A study on the effect of environmental toxins on members of nearby communities involves analysis of toxin levels in discarded hair clippings from barber shops in the communities. What should the researchers and REBs consider in managing the consent process?

- Is an exception to the requirement to seek prior consent justified?
- Should there be debriefing after the study?

(Art. 3.7A – 3.7B)

2a. Consent (4/4)

Broad consent

- Applies to the storage and secondary use of participants' data and human biological materials for all types of future unspecified research, subject to specific restrictions.
- In the context of future research using data and human biological materials with no direct contact or intervention with participants at that time.
- Addition of a new section and article in Chapter 3 and new definitions

(Art. 3.13)

2b. Fairness and equity in research participation

Special inclusion considerations - research involving communities

- Appropriate Inclusion: based on scope and objectives of the research
- Inappropriate exclusion: based on culture, language, religion, race, disability, sexual orientation, gender, age or ethnicity, unless there is a valid reason for the exclusion
  - Inadvertent inclusion of people in research who do not meet the inclusion criteria
    - Ways to narrow exposure: observational methods, census data
  - Recruitment that is visible or affects the entire community and cannot exclude non-targeted members
    - For example, use of billboard ads or radio broadcasts.

Scenario # 2 – Balancing risks and benefits (1/2)

A researcher plans to study the prevalence of sexually transmitted infection in a specific neighbourhood. How should they consider the risks and benefits of this research?

- Risks and benefits must be considered from the perspective of the participant, the community, and other resident members of the community.

Scenario # 2 – Balancing risks and benefits (2/2)

	Risks	Potential Benefits
Participants	emotional distress	can seek treatment
Neighbourhood	stigmatization	can take steps to minimize risks of infection
Other residents	stigmatization by association	may have access to resources

- Researchers should engage with the community, minimize risks of research to participants, the community and other residents of the community.

2d. Privacy and confidentiality

Privacy: an individual's right to be free from intrusion or interference by others

Privacy risks: the potential harms that participants may experience from the collection, use, and disclosure of personal information

Confidentiality: the responsibility to safeguard information from unauthorized access, use, disclosure, modification, loss, or theft.

- Researchers have an ethical duty of confidentiality (Art. 5.1)
- Meeting confidentiality obligations and explaining any reasonably foreseeable disclosure requirements (Art. 5.2)

Privacy and confidentiality considerations

- How will the researcher protect identifiable information?
- Does the location of the research present a privacy risk?
- What protections are in place for the storage and transfer of collected data?
- Who has access to the data?
- Will participants be identifiable in the dissemination of the results?
- For how long will the researcher keep the collected data?
  - TCPS does not require a specific duration for data retention.

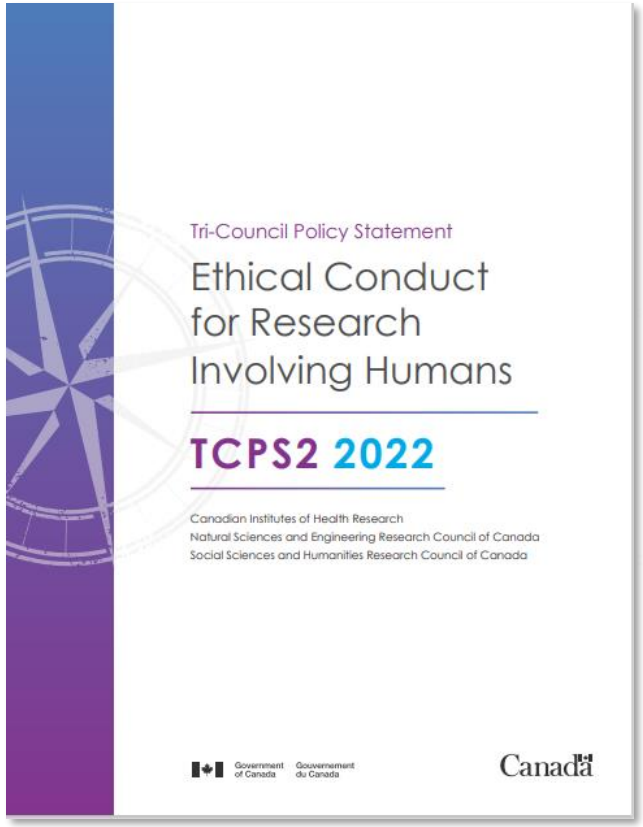
Other considerations

- Indirect identifiers
- Data linkage
- Legal or professional disclosure requirements
- Relevant privacy laws

Tips for researchers

Researchers have a responsibility “to ensure that research involving humans meets high scientific and ethical standards that respect and protect the participants” (Chapter 1, Section A)

- **Plan time for community engagement**
  - Develop an understanding of the group/population of interest (including their values and culture; manage language barriers)
  - Develop awareness of relevant cultural practices
- **Work with your REB**
  - Consult your REB informally, ahead of the formal REB review.
  - Inform your REB of your strategies to familiarize yourself with the relevant norms and cultural practices of the community.



THANK YOU!

Secretariat on Responsible Conduct of Research

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https://ethics.gc.ca