# Research Ethics Review

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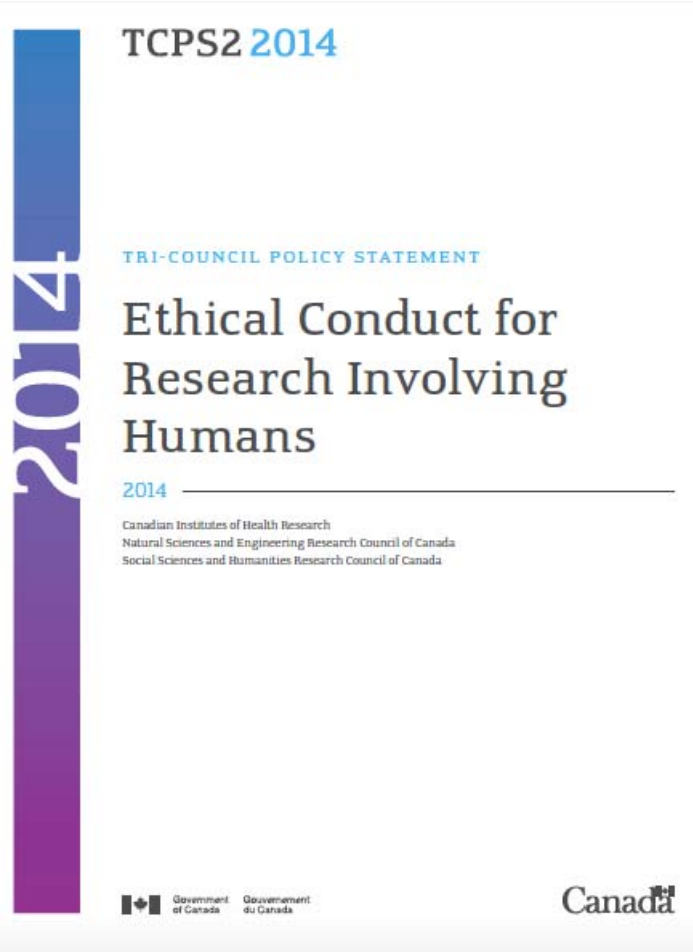
# Topics

- Research and REB review
- Walking through the path of research ethics review.

# Guiding Principles TCPS2 2014



TCPS2 2014

2014

TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2014

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Government of Canada Gouvernement du Canada

Canada

# Walking through an REB form
# and
# Process of review at the REB committee

## Welcome sunny path

## Unwelcome scary path

ROMEO
Award and Certification Portal

## Delegated versus Full review

Full Review:

- Aboriginal people
- At risk populations (youth, elderly, cognitively impaired)
- Invasive experiments – any experiment that offers more harm than that experienced during your daily life

Delegated Review:

- Explain in detail why it should be delegated

# Delegated review

- **Reviewed by 2-3 REB members – Each person reviews the entire proposal**
  - They read the proposal individually and comment on any ethical concerns
  - Review each part– surveys, posters, consent forms – anything the patients/participants see – don't submit with missing pieces
- **No significant concerns**
  - Comments submitted to the Chair and Chair summarizes for the researcher
  - Researcher given the opportunity to address and make changes where required. Sometimes these changes are significant. Sometimes they are minor
- **Researcher**
  - Resubmits through ROMEO
  - In addition, the researcher is required to submit a summary of changes
- **If the Chair is satisfied with edits, an approval letter will be granted to allow the project to proceed.**
- **Will go to Full review if**
  - The reviewers feel they don't have enough information, or it lacks clarity, organization or they have serious concerns, they can ask that it be brought to a full board review
  - The Chair requests Full review

# Full review

- Monthly meetings
- No summer meetings
- Board consists of
  - community member (lay person) – no affiliation with the institution,
  - 2 members with expertise in the field
  - 1 member with expertise in ethics
  - 1 member with legal expertise
  - Aboriginal expertise must be present for overview of files including Aboriginal content
  - REB size grows with respect to the growth of files reviewed

# Full review – Round Table Discussion

- REB members read every proposal
- Researcher will be given 10 minutes to summarize their project
- Round Table –
  - Each board member will identify their concerns with the project
  - Researcher is not expected to answer or explain these concerns
- Researcher receives a list/summary of concerns within a week after the meeting
- The purpose is to highlight the many views/perspectives, ensure research participants and researchers are protected during their project

**The round table 'discussion' can last 30 - 60 minutes**

# Full Review – outcome

- Within a week of the meeting the Chair will summarize the boards decision:
  - Recommend project proceeds with specific changes
  - Recommend project is not eligible to proceed – does not happen often.
- Revisions
  - May be substantial
  - Are required to receive ethics approval
- Approval
  - Revisions submitted to the Chair (like delegated review)
  - Sometimes the project is requested to return to the full board for re-approval – e.g., high risk or at-risk populations.

# MAKE NOTE

- Reviewer may spend 1 hour reviewing and compiling notes on your project
- Make it simple for them to approve your project by completing the form properly
- Answer the questions to the point – but be clear –
- Don’t give them any reason to comment on your proposal
- Double check your spelling and grammar
- Don’t use abbreviations – remember – 2 members of the board are lay people, you may have them review your application
- Write your consent form and any advertising as if it were to a grade four student – short sentences lots of space.

# Consent Form: All these points must be included

- This form explains what would happen if you join this research study.
- Please read it carefully.  Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your care.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at anytime.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.
- Your information will be kept confidential, and if you choose to leave the study you can remove your information if you decide to.
- How will the information be maintained confidential?
- Explain the purpose of the study
- Explain the numbers of participants and what is expected of them, how long they are expected to be in the study – total time commitment, any potential risk and how it will be mitigated
- What are the benefits?
- Is there any cost to participate?
- Are there any incentives?
- Contact numbers of the Primary investigator, the REB need to be included
- How will the results of the study be disseminated?