

Highlights of TCPS 2

Comparing TCPS 2 to the 1st edition

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) is the joint research ethics policy statement of the federal research agencies – Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and Social Sciences and Humanities Research Council of Canada (SSHRC). TCPS 2 is the first comprehensive revision of this Policy since its adoption in 1998. This document highlights some of the key elements of TCPS 2 in relation to the 1st edition.

What is the same?

- underlying value of respect for human dignity as basis for the core principles
- scope of research ethics review
- proportionate approach to research ethics review
- respect for academic freedom and acknowledgement of associated responsibilities
- respect for the law and the need to balance it with ethics principles
- requirement for free, informed and ongoing consent
- responsibilities associated with participant privacy and information confidentiality
- fundamentals of research ethics board (REB) governance
- conflict of interest requirements

What has changed?

- core principles consolidated
- guidelines updated in the areas of:
 - clinical trials
 - human biological materials
 - human genetics
- terminology (e.g., “participant” instead of “subject,” or “delegated review” instead of “expedited and departmental reviews”)



What is new?

- three chapters
 - Multi-Jurisdictional Research (Chapter 8)
 - Research Involving First Nations, Inuit and Métis Peoples of Canada (Chapter 9)
 - Qualitative Research (Chapter 10)
- clinical trial registration
- research ethics review during publicly declared emergencies
- institutional responsibilities associated with security of information
- reporting incidental findings
- research directives
- document structure
- index and glossary

What has been clarified?

- scope of REB review, including exemptions
- increased emphasis on principles and proportionate approach to research ethics review
- REB independence
- consent requirements
- continuing research ethics review
- critical inquiry
- roles and responsibilities of those involved in the research process