



Government  
of Canada

Secretariat on Responsible  
Conduct of Research

Ottawa, Canada  
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Gouvernement  
du Canada

Secrétariat sur la conduite  
responsable de la recherche

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# Highlights of Changes

Proposed Revisions to the 2<sup>nd</sup> edition of the

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

**TCPS 2 (2014)**

October 14, 2016 to January 31, 2017

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## **Chapter 2 – SCOPE AND APPROACH**

- Define “pilot studies” and emphasize the requirement for REB review
- Clarify the different types of observational research, introducing a description of epidemiological studies
- Add article that exempts course-based research pedagogical activities from REB review
- Add guidance on research-attributable risks and research benefit misconception
- Add guidance addressing research involving communities

## **Chapter 3 – THE CONSENT PROCESS**

- Clarify that recruitment is a step in the consent process
- Add guidance regarding community-level interventions

## **Chapter 4 – FAIRNESS AND EQUITY IN RESEARCH PARTICIPATION**

- Add guidance emphasizing the requirement to disseminate research results

## **Chapter 5 – PRIVACY AND CONFIDENTIALITY**

- Clarify guidance on institutional support for researchers’ ethical duty of confidentiality

## **Chapter 6 – GOVERNANCE OF RESEARCH ETHICS REVIEW**

- Add guidance on the review of sponsor-researcher contracts
- Clarify guidance for pilot studies
- Change guidance regarding delegated review



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## **Chapter 7 – CONFLICTS OF INTEREST**

- Add guidance on the role of the REB in the review of financial conflicts of interest in research
- Add guidance regarding community conflicts of interest

## **Chapter 10 – QUALITATIVE RESEARCH**

- Clarify the type of observational studies referred to within the context of the guidance

## **Chapter 11 – INTERVENTIONAL RESEARCH (formerly Clinical Trials)**

- Introduce revamped chapter with a wider scope. Includes research beyond clinical trials that involves prospective assignment of participants to one or more interventions, and research that presents more-than-minimal risk to participants
- Preserve guidance that specifically applies to clinical trials in a separate section of this chapter

## **Glossary**

- Introduce new and revised definitions that reflect proposed changes to the Policy

## **Other Minor Changes**

### **Terminology**

- Certain terms have been revised throughout the text, such as “individuals in vulnerable circumstances” being changed to “individuals whose circumstances may make them vulnerable in the context of research.”

### **Examples**

- Add examples to reflect public health research