

What's New in the TCPS?

The draft 2nd edition is the first attempt at a comprehensive revision to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) since its adoption in 1998 by Canada's three research Agencies. The following are highlights of changes proposed in the draft 2nd edition.

Principles

- emphasize respect for human dignity and proportionality of ethics review;
- eight principles have been distilled into three core principles:
 - o concern for welfare;
 - o respect for autonomy;
 - o respect for equal moral status of all humans.

Structure

- framework changed from an introduction and 10 sections to 13 chapters;
- emphasizes importance of principles;
- articles simplified;
- each article followed by an application;
- scope of the Policy defined more explicitly, including clarification on which types of activities are *not* subject to research ethics board review, such as creative practice activities;
- cross-references provided to facilitate interpretation.

Terminology

- changes in usage such as "research participant" rather than "subject" and "delegated review" rather than "expedited review" and "departmental review;"
- improved definitions for existing terms such as the definition of research as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation" to include social sciences and humanities research;
- additional definitions, for example, for clinical trials and all phases of clinical trials, personal information and the categories of information;
- inclusive language and examples used to encompass *all* types of research involving humans and a broad spectrum of research approaches.



Guidelines Updated

- certain fields of research such as research with human tissue, human genetic research;
- specific issues such as privacy and confidentiality, secondary use of research data or materials, stem cell research, the adoption of CIHR guidelines.

New Chapters

- research involving Aboriginal Peoples including guidelines for community engagement;
- qualitative research, including discussion of how the core principles are to be applied.

Interpretations and Consultations Integrated

- responses to interpretation questions developed over the last few years;
- recommendations from working committee reports based on public consultations.

New Provisions

- clearly identified in the Table of Concordance (2008 to 1998). The Table indicates where no comparable article or commentary existed in 1998 edition of the TCPS;
- address concerns expressed by researchers and REB members, such as the expanded discussion of models for review of multi-jurisdictional research;
- address concerns that have arisen in research ethics, such as the need for more explicit guidelines concerning sharing of new information in the course of research, particularly in clinical research, following the Olivieri case.

The Panel and Secretariat on Research Ethics are eager to hear from those who use the TCPS, in order to improve this draft before presenting a final version to the three Agencies for approval and adoption. Please send your comments on the draft 2nd edition of the TCPS to draft2e@pre.ethics.gc.ca . The consultation period ends March 31, 2009.