

## Where are we at with the TCPS? Reflections at the crossroads

Susan V. Zimmerman  
Executive Director  
Interagency Secretariat on Research Ethics

CAREB Annual Meeting  
Friday, April 30, 2010  
Montréal, QC



**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Evolution of the TCPS: 1998 - 2010

- 1998: Agencies issue a joint policy statement on the ethical conduct of research involving humans (TCPS-E)
- 2001: Agencies establish the Panel on Research Ethics supported by an Interagency Secretariat to oversee the evolution and interpretation of the TCPS-E
- 2002-2008: committees of the Panel work draft papers and make recommendations on specific issues requiring revision
- December 2008: **Panel issues draft 2<sup>nd</sup> edition** – major revision of TCPS
- Dec. 2008 – June 2009: first round of public consultations
- December 2009: **Panel issues revised draft**
- Dec 2009 – Feb. 2010: 2<sup>nd</sup> round of public consultations
- May 2010: **Panel to provide final draft to Agencies**
- May – June 2010: Agency consideration and approval

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Goal of the TCPS

“This Policy aims to assist those who use it – researchers, sponsors, members of research ethics boards, research participants and the public – to identify ethical issues in the design, conduct and oversight of research and to point the way to arriving at reasoned and ethical responses to these issues.”

- Chapter 1, “Ethics Framework”

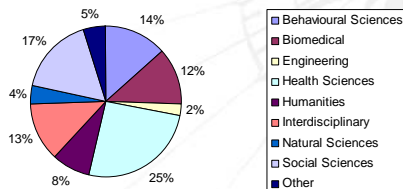
**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Feedback from the research community

- Consultations (2008)
  - 58 consultations and conference presentations
  - 17 cities
  - estimated attendance: 1,780 people
- Written comments (2008 and 2009)
  - More than 360 submissions
  - More than 1,800 pages of notes and comments

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Consultation: Participant Disciplines



**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Main Changes in TCPS Draft 2<sup>nd</sup> Edition

- Principles consolidated
- Structure re-organized
- Guidelines updated
- Interpretations integrated
- Chapters added
- Terminology and examples modified to better reflect research disciplines of all three Agencies

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## 2<sup>nd</sup> round of public comments

Some examples of what you liked:

- Revised core principles
- Revised conditions re when those who lack capacity may participate in research
- Revisions re secondary use of data without consent

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## 2<sup>nd</sup> round of public comments (cont'd)

Some areas that received more comments:

- The chapter on clinical trials
- The chapter on research involving Aboriginal Peoples
- Our failure to encourage research involving pregnant women

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Striking a balance

- Substantial change without further input risky
- Putting off necessary changes also risky
- Panel did make important changes
- Some issues flagged as priorities for further evolution

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## Sample of what you can expect in final draft

- substantial changes to Aboriginal chapter
- substantial changes to clinical trials (now clinical research) chapter
- Additions to chapter on fairness and equity in research
- Greater discussion of financial conflict of interest in COI chapter (not just in CT chapter)

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## So near, yet...

- Final revisions being made to Chap. 11
- Final review by Dept of Justice in progress
- Delivery to Agencies sometime in May
- Agencies aiming to review and approve through their respective processes by end of June

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

## What's next for the Panel

- Facilitating transition (e.g. interpretations, advice on revising institutional policies)
- Implementation through education
- Addressing specific issues
- Staying in touch

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

Progress made, challenges ahead



**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research

How to reach us



**PANEL ON RESEARCH  
ETHICS**

350 Albert Street  
Ottawa (Ontario) K1A 1H5  
Tel.: 613 996-0072  
secretariat@pre.ethics.gc.ca  
www.pre.ethics.gc.ca

**PANEL ON  
RESEARCH ETHICS**  
Navigating the ethics of human research