

Secretariat on Responsible Conduct of Research: Current Initiatives

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**PANEL ON
RESEARCH ETHICS**

Navigating the ethics of human research

Snapshot of Secretariat/PRE work

- Two initiatives ready for consultation:
 - Ch.11 – Clinical Trials
 - population and public health research
- Progress on three newer initiatives:
 - research involving cell lines
 - material incidental findings; and
 - research participant education

Chapter 11 and PPH

- identified as priority areas during 2010 revision of TCPS
- expert advisory sub-committees gave both policy and practical advice

Highlights of recommended changes

Expand scope of clinical trials chapter to include studies that meet both of the following criteria:

- the methodology includes prospective assignment to one or more interventions; and
- one or more interventions involve more than minimal risk to participants.

Highlights of changes (cont'd)

- Move some guidance from Ch.11 to more general chapters:
 - Research benefit misconception;
 - Research-attributable risk;
 - Requirement to disseminate findings.

Highlights of changes (cont'd)

- Add guidance in the areas of:
 - community based research;
 - recruitment;
 - pilot studies;
 - sponsor-researcher contracts.

Highlights of changes (cont'd)

- Add guidance in the areas of:
 - community based research;
 - recruitment;
 - pilot studies;
 - sponsor-researcher contracts
- Add population and public health examples.

Chap. 11 – social science perspective

- Discussion group of social scientists formed when it became clear that the Chap. 11 subcommittee was going to advise expanding the scope of the chapter beyond clinical trials
- Their input served to reflect the different perspectives of social scientists conducting interventional trials of more than minimal risk

Chapter 11 Advisory Committee

- Michel Bergeron, Université de Montréal (PRE)
- Anne Dooley, former Panel Member representing participants
- Carolyn Ells, McGill University (PRE Chair)
- Michael Farkouh, University Health Network
- Larry Felt, Memorial University (PRE)
- Martin Schechter, University of British Columbia (PRE)
- Veronica Stinson, Saint Mary's University (PRE)
- Lehana Thabane, McMaster University (PRE)

Social Sciences Discussion Group

- Christopher Ksoll, University of Ottawa
- Michael Leiter, Acadia University
- Michael Noseworthy, McMaster University
- Wendy Rodgers, University of Alberta
- Katreena Scott, University of Toronto

Population and Public Health Research Advisory Sub-committee

Recommendations included:

- providing more PPH examples where relevant throughout TCPS
- adding TCPS 2 guidance in areas such as research involving communities, recruitment and the fair distribution of benefits and burdens
- preparing a public interpretation about public surveillance

Population and Public Health Research Advisory Committee

- Lina Al-Karkhi, PHAC
Judith Bartlett, Faculty, University of Manitoba (PRE)
- Michel Bergeron, Université de Montréal (PRE)
- Michel Désy, Université de Montréal
- Nancy Edwards, Institute of Population and Public Health
- France Eduardo, McGill University
- Carolyn Ells, McGill University, (PRE Chair)
- Larry Felt, Memorial University (PRE)
- Ian Gemmill, KFL&A Public Health
- Mireille Lacroix, PHAC
- Marjorie MacDonald, University of Victoria
Nazeem Muhajarine, University of Saskatchewan
- Paulette Richard, PHAC
Martin Schechter, University of British Columbia (PRE)
- Ross Upshur, Dalla Lana Faculty of Public Health
- Sarah Viehbeck, Institute of Population and Public Health
Don Willison, University of Toronto
- Brent Windwick, University of Alberta (PRE)

Cell Line Advisory Sub-committee



Mandate:

to determine whether an exemption from REB review is required for research involving the secondary use of human cells, including cell lines.

Approach of CLAS

1. Achieve a common understanding of the relevant terms.
2. Discuss the ethical issues associated with research involving human cells.
3. Understand relevant guidance in other jurisdictions.
4. Discuss possible solutions and determine proposed solution.
5. Test proposed solution by applying guidelines to ATCC
6. Apply principles of cell solution to human biological materials.
7. Prepare final recommendations for PRE

Members of CLAS

- Lorne Babiuk, University of Alberta (U15)
- Mick Bhatia, McMaster Stem Cell and Cancer Research Institute,
- Michael Hill, University of Calgary
- David Hoskin, Dalhousie University,
- Stacey Page, University of Calgary (CAREB)
- Daryl Pullman, Memorial University
- Dr. Josie Ursini-Siegel, McGill University
- Barbara von Tigerstrom, University of Saskatchewan (SCOC)

From PRE:

- Carolyn Ells, McGill (Chair of PRE)
- Lehana Thabane, McMaster

Incidental Findings Sub-committee

- Arose out of feedback received in 2014 consultation
- Concern re role of REB in identifying MIF
- Lack of consensus on responsibilities of researchers faced with MIFs

Incidental Findings Sub-committee

- Mandate: identify gaps, clarifications and any required revisions to MIF in TCPS 2
 - Expert advice on MIF
 - Comments from public consultation
 - Literature on MIF
- Progress: started in October 2015, reporting to PRE on its strategy in June 2016

Members of Incidental Findings Sub-committee

- **Wylie Burke** -University of Washington
- **Conrad Fernandez** - Dalhousie University
- **Judy Illes** - - University of British Columbia
- **Wendy Pelletier** –Alberta Children’s Hospital
- **Alice Virani** –Children's and Women's Hospital of British Columbia
- **Ma’n Zawati** - McGill University

From PRE:

- **Carolyn Ells (Chair)** - McGill University
- **Brent Windwick** -Field Law, Alberta

Research Participant Education Sub-committee (RPES)

- Purpose: to advise PRE on educational initiatives for those contemplating participation in research
- Number of tools identified as potentially useful
 - Developed outline for a tutorial module
 - tutorial platform delayed
 - Focus has shifted to:
 - basic brochure: Taking part in research
 - set of FAQs for research participants

Members of RPES

- **Paula Barata** - *Applied Social Psychology, University of Guelph*
- **Michel Bergeron** – *Ethicist, Université de Montréal REB*
- **Joan Boutilier** - *Community member - Acadia University's REB*
- **Anne Dooley** - *Volunteer health care and patient advocate, Saskatchewan*
- **Conrad Fernandez** – *Paediatrics - Dalhousie University*
- **Heather Fowlie** – *Community member - UBC Children's and Women's REB*
- **John M. H. Kelly** – *Journalism - Carleton University*
- **Pat Maddocks** – *Patient advocate and volunteer*
- **Michael McDonald** – *Population and Public Health - UBC*
- **Richard Sugarman** - *University of Toronto and OCREB*
- **Andrew Zealley** - *Toronto-based interdisciplinary artist and activist*

From PRE

- **Gordon Robinson** - *RPES Co-Chair – Research Participant*
- **Veronica Stinson** - *RPES Co-Chair- Psychology- Saint-Mary's University*

Interpretations and Education on TCPS 2

Interpretations

- Responses to individual requests for interpretation
- Publicly posted interpretations:
 - Now 46 interpretations – both languages
 - New categories, e.g. multi-jurisdictional research

Education

- Release of two new educational modules in pdf format:
 - Research Involving FNIM
 - Multi-jurisdictional research

REB survey

Themes:

- More education about the application of TCPS principles
- Increase availability of examples and interpretations
- More TCPS guidance required in the areas of:
 - Definition of research vs. QA, creative practice, etc.
 - Role of REB with respect to academic review
 - Research involving social media

Please get in touch



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