Ethics in Research with Humans

SAINT MARY'S UNIVERSITY SINCE 1802

One University. One World. Yours.

“Research”

An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

“Participant”

An individual whose data, or responses to interventions, stimuli or questions by a researcher are relevant to answering a research question.

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2014)

TCPS 2:

http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/default/

CORE tutorial: Course on Research Ethics (CORE Tutorial):
http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

TCPS2 2014

2014

TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2014

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Government of Canada / Gouvernement du Canada

Canada

TCPS 2: Core Principles

- Respect for persons
  - Autonomy/voluntary
  - Informed decisions/Competence
  - Lack of pressure
- Concern for welfare
  - Privacy and control over information
  - Foreseeable risks
- Justice
  - Treating people fairly & equitably
  - Distributing benefits & burdens equitably
  - Vulnerabilities
  - Imbalance of power between researcher and participant

How can we apply the TCPS 2 Principles of ethical research?

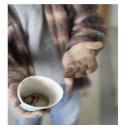
- Assessing Benefits
  - Identify benefits honestly: direct & indirect
  - What is the potential for advancing understanding? Be realistic.

- Assessing Risks
  - Identify and anticipate potential risks: physical, psychological, economic, social
  - Potential magnitude of harm or seriousness of harm (minimal harm? Life-threatening harm or death?)
  - Likelihood (low likelihood? High likelihood?)

- Informed Consent Process
  - TCPS, Chapter 2, Article 3.2
  - Use sample informed consent form if possible
  - Signed Informed Consent form vs. Information Letter (unsigned)
  - Withdrawal issues
  - Feedback to participants
  - Use sample Feedback form if possible

- Data Security
  - "Identifiable" / "personal" versus non identifiable data (Data Custodians)
  - Gathering, retention, travel, storage, dissemination, destruction



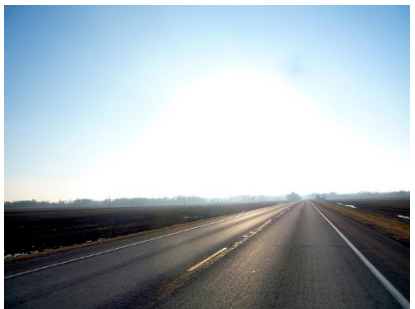


Bumps to avoid…

- Applications are not signed
- Documents are missing
- Informed consent form/script is difficult to understand, missing information, incomplete, inadequate
- Intentions are not harmonized with supporting documents
- Intentions are not listed in a sequential and comprehensible way
- Benefits are overstated or understated
- Risks aren’t recognized, vulnerability of a person is not recognized
- There isn’t a solid plan involving adverse events, help is not in place for participants, researcher is unprepared for foreseeable situations
- Questions are left blank in place of properly selecting “N/A”

Smooth ethics review process is most likely when…

- Think carefully about what you want to do. Tell us about it clearly – no jargon.
- Explain why you're doing your research (benefits)
- Think about and explain potential risks
- Complete the application carefully
- Use the sample Informed Consent Form and sample Feedback letter as a template (feel free to modify to your liking, but ensure the key info is there)



Have questions? Need help? Want to chat about your research?

Orshy Torok, Research Ethics Officer
ethics@smu.ca, Atrium 202