Does My Project Require Review? Research Ethics at UBC

Master of Health Administration

Jean Ruiz, MA
Senior Research Ethics Analyst - Behavioural
Office of Research Ethics

a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Overview

- TCPS2
- Research that requires review
- Research not requiring review
- Activities not requiring review
- Scenarios
- Secondary use of data
- Quick Overview of BREB process

TRI COUNCIL POLICY STATEMENT

- Overarching Canadian policy framework for research involving human participants
- All researchers should be familiar with TCPS2(2014)
- TCPS guidelines recently revised and the latest addition was released in Dec. 2014.
- TCPS2 available at: http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/
- TCPS2 Tutorial ('CORE') available at: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

What is research?

- "Research is an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation" (TCPS2-2014, Article 2.1)
  - The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.
  - Explicit focus on *intention* of researcher as distinguishing factor between research & other activities that look research-like

Research that Requires Review

TCPS2 Article 2.1:

a. "Research involving human participants;
b. Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals."

Human Participant

- Those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research questions

Note: "Research may involve interactions with individuals who are not themselves the focus of the research in order to obtain information. For example, one may collect information from authorized personnel to release information or data in the ordinary course of their employment about organizations, policies, procedures, professional practices or statistical reports. Such individuals are not considered participants for the purpose of this Policy. This is distinct from situations where individuals are considered participants because they are themselves the focus of the research." (TCPS2, Article 2.1 Application Section, p. 16)

Research Exempt from Review (TCPS2-2014, 2.2)

- "Research that relies exclusively on publicly available information does not require review when:
  - The information is legally accessible to the public and appropriately protected by law; or
  - The information is publicly accessible and there is no reasonable expectation of privacy"

Note: Archival record or database that is subject to restrictions, such as those under access to information and privacy legislation or contractual restrictions imposed by the donor of the records, may also be considered publically available for the purpose of this Policy

Activities not requiring review

- QA/QI studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do NOT constitute research (TCPS2 - 2014, 2.5)
  - These activities are generally “assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training.”
  - But they “may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB”
  - NOTE: You may still need institutional approval for studies conducted within the Health Authorities

QA/QI vs. research

- Such studies do NOT require ethical review unless they contain an explicit research component
  - Checklist: http://research.ubc.ca/sites/research.ubc.ca/files/uploads/BREB_ChecklistForResearchRequiringEthicsReview.pdf
    - Randomization?
    - Presentation as 'research'?
    - Rigorous enough to support generalizations?

Scenario #1

- You work for the Ministry of Health. One of the projects you have worked on was a campaign project against the overuse of antibiotics
- You develop an interest in the area and decide to base your capstone project for you MHA degree on how culture and mass media influence how people make decisions about their health. You will use the antibiotics campaigns as a case study
- You design a study that looks at similar programs run across Canada. You compare and contrast the different elements of the campaigns and compare prescription rates at area hospital emergency rooms for antibiotics before and after the programs were initiated.
- You also conduct a focus group around incentive and the types of things that influence people when it comes to making decisions around their health

Scenario #2

- You are a UBC graduate student in the Faculty of Medicine and also work for UBC Hospital as an administrator
- The hospital pharmacy asks you to look at medication adherence amongst elderly who regularly have their prescriptions filled at the pharmacy and a program that has been in place for sometime to promote this. The hospital wants to gather feedback on how the program is working.
- You design a study involving a detailed questionnaire, including listing present prescriptions, followed by a focus group, which will be recorded.
- People who participate in the program are given an information pamphlet when they have their prescriptions filled describing the study. They are asked to contact you, if they are interested in participating.
- The results of the study will be used to inform how the program is working and what could be improved. You will also use this project to fulfil your requirements for your capstone project (non-thesis based)

Scenario #2 continued…..

- What if you want publish?
- The results of your study suggest that men between 70-85 do not benefit from the program in the same way as women in the same category. If this is true in other hospitals with like programs, this may be useful information to share more broadly. Your supervisor suggests that you increase your sample size, including other hospital pharmacies, and consider publication in a scholarly journal.
  - Is this still evaluation? Why or why not?
  - How can you use your evaluation data for research purposes?

QA/QI studies & publication

- Intended publication is NOT litmus test for BREB review
  - *British Medical Journal:* "Details of ethical approval (or a statement that it was not required)"
  - *American Journal of Evaluation:* "Has the research been subject to appropriate ethical review? If Yes, please provide the name of the ethical review board in the box below. If No, please explain why ethical approval was not obtained in the box below."
- Response: "Under Article 2.5 of the Tri Council Policy Statement QA/QI studies are not classified as research and are exempt from institutional ethical review"

Secondary use of data

- Data collected for QA/QI or educational purposes but later proposed for research would be considered **secondary use of data**
- Secondary use of anonymously collected data
  - Ethics review not required (see TCPS article 2.4)
- Secondary use of identifiable data
  - Ethics application for secondary use of data must be submitted
  - Application can be submitted as minimal risk study (average turnaround: 3 weeks)
  - Waiver of informed consent can be requested (See TCPS2-2014, article 5.5.A. and B.)

BREB REVIEW

RISe

- All applications and associated documents must be submitted online
- RISe (Researcher Information Services): http://rise.ubc.ca/
  - From RISe homepage follow the link on the right hand side "Accessing RISe"
  - Need campus-wide login (CWL) Account
    (http://www.it.ubc.ca/cwl/homelink.shtml)
  - Need Researcher # from ors@ors.ubc.ca

ETHICS REVIEW CATEGORIES

- Minimal risk
  - No greater than risks of everyday life
  - No deadlines for minimal risk (reviewed by academic members)
- Full board
  - meets once a month (ever 2nd Thursday)
  - Check website for deadlines (http://www.ors.ubc.ca/ethics/behavioural/b-deadlines.htm)

What studies would not be minimal risk?

- Under new guidelines MOST social science/behavioural research is expected to meet minimal risk guidelines
- Except research that involves **BOTH** vulnerable populations **AND** personal, sensitive or incriminating topics or questions
  - Studying people engaged in illegal activities (e.g. heroin use or euthanasia) about these activities
  - Experiences of bullying amongst school-aged children
  - Talking to abused people about their experiences of abuse
- Research that uses deception
  - *Unless* researcher has convincingly argued that deception is minor & possibility of harm is remote

Minimal Risk Matrix

➔	**Research Risk: Physical, Emotional, Psychological, Financial, Legal, Privacy, Reputation, Group**		
Vulnerability	**Low**	**Medium**	**High**
Low	Delegated	Delegated	Full board
Medium	Delegated	Full board	Full board
High	Full board	Full board	Full board

WHAT HAPPENS ONCE MY APPLICATION IS SUBMITTED?

Application submitted

↓

→ Reviewed by Department Head ←

↓

Appears in research ethics board administrators' inbox :

Minimal risk studies → Associate Chair reviews

Full board studies → 2 primary reviewers → reviewed at board meeting

↓

Approved – certificate of approval

→ Provisos (Amendments) *most common scenario ←

Deferred – provisos with responses to be reviewed by full board

↓

Study can begin

KEY RESOURCES

- ****Behavioural Research Ethics Board guidance notes****
  - Available from: http://research.ubc.ca/ore/breb-forms-guidance-notes
  - Read ***before*** submitting an application
- TCPS Tutorial: Course on Research Ethics (CORE) http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

Consultation

- Jean Ruiz, Senior Research Ethics Analyst - Behavioural
  Ph: 604 827 5310, Email: jean.ruiz@ors.ubc.ca

- Shirley Thompson, Manager of BREB
  Ph: 604 827 5112, Email: shirley.thompson@ors.ubc.ca

- Nadia Rad, Senior Administrative Coordinator
  Ph: 604-827-5114; Email: nadia.rad@ors.ubc.ca