TCPS 2: What's in it for you

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Objectives

- Provide an overview of 2nd edition of Tri-council Policy Statement
- Discuss scope of TCPS2 and its definitions of research, including activities that are exempt from REB oversight
- Discuss other specific areas of change and their implications on research
- Encourage open discussion through questions and case studies

Canadian Research Ethics Guidelines

- Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)
- Overarching Canadian policy framework for research involving human participants
- 1st TCPS came out in 1998; revised version released Dec. 2010
- TCPS2 available at: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/
- TCPS2 Tutorial ('CORE') available at: http://pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

Guiding Ethical Principles – TCPS1

1. Respect for Human Dignity
2. Respect for Free and Informed Consent
3. Respect for Vulnerable Persons
4. Respect for Privacy and Confidentiality
5. Respect for Justice and Inclusiveness
6. Balancing Harms and Benefits
7. Minimizing Harm
8. Maximizing Benefit

Ethical Principles – TCPS2

1. Respect for persons

- Free and informed consent
- Protecting those with developing/diminished autonomy

2. Concern for welfare

- Consideration of impact on physical, mental, and spiritual health, as well as participants' physical, economic and social circumstances
- Consider risks & potential benefits of research

3. Justice

- Obligation to treat people fairly & equitably
- Equal access to benefits/equal share of burdens
- Avoid under protection & overprotection

Major Changes

- Although 8 principles collapsed into 3 overarching ones, the spirit of original principles is evident in new ones
- De-emphasizes the original "subject-centred" approach of the TCPS1
  - TCPS2 emphasizes welfare of groups to which individuals belong, as well as individuals themselves
- Approach to benefits and harms has shifted slightly in TCPS (to a "favourable balance")
  - Critical Inquiry

Definition of Research

- **TCPS 1** (article 1.1)**:** "Research involves a systematic investigation to establish facts, principles or generalizable knowledge"

- **TCPS 2** (article 2.1)**:** "Research is an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation"

Major Changes

- Emphasis on generalizability has been removed
- More explicit focus on *intention* of researcher as distinguishing factor between research & other activities that look research-like

Definition of Participant

- **TCPS 1** (article 1.1): "The term 'research subjects' refers to living individuals"

- **TCPS 2** (article 2.1): "Human participants are those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question"
  - "In some cases, research may involve interaction with individuals who are not themselves the focus of the research in order to obtain information… Such individuals are not considered participants for the purposes of this policy"

Major Changes

- Ideological shift from ‘subjects’ to ‘participants’
- A delimited definition of research participants has now been provided
- Personnel authorized to release information or data in ordinary course of their employment are not deemed to be research participants
    - Unless you are seeking information on their personal opinions/perspectives

Research Exempt From REB Review

- **TCPS 1** (article 1.1 & article 2.3)
  - Research about a living individual involved in the public arena… based exclusively on publicly available information, documents, records, works, performances, archival materials, or third party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this Policy.
  - REB review is normally required for research involving naturalistic observation. However, research involving observation of participants, in for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

- **TCPS 2** (articles 2.2-2.4)
  - Research that relies exclusively on publicly available information does not require review when:
    - The info is legally accessible to public & appropriately protected by law;
    - The info is publicly accessible & there is no reasonable expectation of privacy.
  - REB review is not required for research involving observation of people in public places where:
    - It does not involve any intervention staged by researcher, or direct interaction with individuals or groups;
    - Individuals or groups targeted for observation have no reasonable expectation of privacy;
    - Any dissemination of research results does not allow identification of specific individuals
  - REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials
    - So long as process of data linkage or recording or dissemination of results does not generate identifiable information.

Activities Not Requiring REB Review

- **TCPS 1** (article 1.1)

•Quality assurance studies, performance reviews or testing within normal educational requirements should not be subject to REB review.

- **TCPS 2** (articles 2.5 & 2.6)

•QA and QI studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes

•Creative practice activities, in and of themselves, do not require REB review.

- **MAJOR CHANGES**

•Further clarification of the QA/QI activities not requiring review – the emphasis is on activities used *exclusively* for assessment and improvement purposes

QA/QI vs. Research

- QA/QI studies do NOT require ethical review unless they contain an explicit research component. What is the intent of the project?
  - Checklists:
    - http://research.ubc.ca/sites/research.ubc.ca/files/uploads/BREB_ChecklistForResearchRequiringEthicsReview.pdf
    - VCHRI: http://www.vchri.ca/i/pdf/Guidance_ResearchEthicsBoard_06Aug2010.pdf
  - Randomization?
  - Presentation as 'research'?
  - Rigorous enough to support generalizations?

Scenario: Research or QA/QI?

- You work in the evaluation studies unit in the Faculty of Medicine at UBC and you want to know whether your program to attract more doctors to rural Canada is working
- You plan to distribute surveys using a relatively comprehensive alumni database to all residents who have graduated since the program's implementation
- You aim to find out where previous students are working, what percentage are working in rural areas
- The results will be used to inform future program planning

Scenario Continued

- The survey has been completed and you discover that gender is strongly correlated with graduates' decision to work in a rural location
- You decide to develop a second survey to deliver to your current students to determine the relationship between gender and their practice preferences post-graduation

Considerations

- Is this QA/QI or research?
- When did it become research?
- Can you use data collected for QA/QI purposes for research purposes?
  - TCPS2 Article 2.5, Application section: "If data are collected for the purposes of QA/QI activities but later proposed for research purposes, it would be considered secondary use of information not originally intended for research"

Relationship Between Ethical & Scholarly Review

- **TCPS 1** (article 1.5)
- The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

- **TCPS 2** (article 2.7)
- As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.
- The primary test to be used by REBs in evaluating a research projects should be ethical acceptability and, where appropriate, relevant disciplinary standards.

Major Changes

- There appears to have been a shift from assessing scholarly merits of projects more generally to focusing on those aspects of the methods and research design that *directly* impact the ethical acceptability of study
- However, prior requirements for research containing more than minimal risk to provide evidence of peer review remain

Proportionate Approach

- **TCPS1**: "The REB should adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research."
- **TCPS2**: "The REB shall adopt a proportionate approach to research ethics review such that, as a preliminary step, the level of review is determined by the level of risk presented by the research: The lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review)." (Article 2.9)

Major Changes

- Level of ethical review corresponds to level of risk research entails
- Explicitly spells out that lower-risk research requires less scrutiny than high risk research & can undergo delegated review

Consent Processes

- **TCPS 1** (article 2.1): "Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing"

- **TCPS 2** (article 3.12): "Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent"
- **TCPS2** (article 10.2, application section): "Under a variety of circumstances, signed written consent is not appropriate in qualitative research"

Major Changes

- Move away from written consent as providing 'ethical standard' for consent
- Recognition that a variety of consent processes are ethical

Scenario: Obtaining Consent

- You plan to study nurses' experiences of working on a pediatric palliative care ward
- You have permission to conduct participant observation on the ward for 6 months and your main data sources will be observations and informal interviews (i.e. informal unrecorded conversations) carried out with nurses on shift during the fieldwork period
- You are concerned about the appropriateness of obtaining written consent from participants
- What are your options?

Considerations for Oral Consent

- It is up to individual researchers to make a case as to what the most appropriate way of obtaining informed consent is and how they will document it
- You should provide REB a script of how you will explain the study to participants and how you ensure that consent is maintained throughout the study
- You may want to consider giving participants an information sheet with a study description and contact information that they do not need to sign, in case they want to withdraw or have a complaint, etc.

Elements of Informed Consent

- **TCPS 1** (article 2.4): "At the commencement of the process of free and informed consent, researchers or their qualified representatives shall provide prospective subjects with the following [standard disclosure statements]"

- **TCPS 2** (article 3.2): "Researchers shall provide prospective participants full disclosure of all information necessary for making an informed decision to participate in a research project"
  - "Not all the listed elements are required for all research" (application section)

Major Changes

- Recognition that flexibility is required in consent forms
- Recognition that some standard wordings may not be appropriate for all studies
- Stronger emphasis on need to tailor consent information to study population

Competence vs. Capacity

- **TCPS 1** (article 2.5): "Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:
  - Research question can only be addressed using individuals within identified group(s)
  - Free & informed consent will be sought from authorized representative(s)
  - Research does not expose them to more than minimal risk without potential for direct benefits for them

- **TCPS 2** (article 3.9): "For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met":
  - Researcher involves participants to greatest extent possible in decision-making process
  - Researcher seeks consent from authorized 3rd parties in accordance with best interests of participants
  - Authorized 3rd party is not member of research team
  - If research does not have potential for direct benefit to participant, should pose only minimal risk & burden;
  - If participant acquires or regains capacity during course of research, researcher should obtain consent before continuing

Major Changes

- Shift from legalistic definition to one based on individual capacity
- Greater emphasis on including participant as much as possible in decision-making processes

Scenario: Capacity for consent

- You are interested in the decision-making processes of 15-year-olds regarding their secondary and tertiary education
- You want to administer anonymous surveys to participants and you would prefer to obtain their direct consent as opposed to seeking parental consent

Considerations

- TCPS2 does not rely on age of majority
- You should be able to make an argument that 15-year-olds have the capacity to make decisions about whether to participate in research
- Provincial legislation does not preclude this (e.g. mature minor doctrine)
- However, depending on the research setting you may still need to obtain parental consent
  - Vancouver School Board requires researchers to obtain parental consent for anyone under 19

Vulnerability

- **TCPS1** (Section 1 C): "Respect for human dignity entails high ethical obligations toward vulnerable persons – to those whose diminished competence and/or decision making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligation to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests."

- **TCPS2** (article 4.7): "Individuals or groups whose circumstances make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances"
  - "However, individuals should not automatically be considered vulnerable simply because of assumptions made about the vulnerability of the group to which they belong. Their particular circumstances shall be considered in the context of the proposed research project"

Major changes

- Intentional change in wording from 'vulnerable persons' to 'vulnerability'
  - http://www.pre.ethics.gc.ca/policy-politique/initiatives/docs/Vulnerability_in_the_TCPS_-_ProGroup_Jan_2008_-_EN.pdf
- Reflects ideological shift from considering vulnerability as an absolute state to something contextual & relational
- Shifts focus from a group concept to the individual context of the participant in question

Secondary Use of Data

- TCPS 1, 3.3: "If identifying information is involved, REB approval shall be sought for secondary use of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:
  a) Identifying information is essential to the research;
  b) They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects; and
  c) Individuals to whom the data refer have not objected to secondary use.
- TCPS 1, 3.4., goes on to state that access to secondary use of data may be dependent on informed consent, demonstrating an appropriate strategy for informing subjects of its use, and consultation with representatives that contributed.

Secondary Use of Data continued

- TCPS2, 5.5: "Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

a) Identifiable information is essential to the research;

b) The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;

d) The researchers will comply with any known preferences previously expressed by individuals about any use of their information;

e) It is impossible or impracticable to seek consent from individuals to whom the information relates; and

f) the researchers have obtained any other necessary permission for secondary use of information for research purposes."

Major Changes

- Clear criteria for a waiver of consent for the secondary use of identifiable data. Note that criteria for secondary use of biological information is more or less the same (Article 12.3).

- The application section of Article 5.5. states "this policy does not require that researchers seek consent from individuals for the secondary use of non-identifiable information."

Multi-Jurisdictional Research

- Chapter 8 gives a green light for consideration of other models besides single-site review
  - Implications: Models need to be in place for researchers to take advantage of this.

- Update on BC's Harmonization effort (funded by Michael Smith Foundation)

Update on BCEHI

- The BC Ethics Harmonization Initiative (BCEHI) continues to make headway on their goal to develop and implement an effective, coordinated, value-added approach to ethical reviews for health research studies requiring multiple research ethics board review within BC.
- The steering committee for the BCEHI was expanded in late spring of 2011 from the original committee of UBC, SFU, and UVic, to include UNBC and 4 health authorities – Northern Health, Fraser Health, Interior Health and Vancouver Island Health Authority. VCH, PHC and PHSA are represented on the committee by UBC, as they have UBC-affiliated REBs.
- The Phase II funding submission to MSFHR in August was successful, which will provide funding for the final four years of the Initiative.
- Patricia Tait was appointed as the director for Phase II in January 2012. She has been seconded to the Initiative by Vancouver Coastal Health. (patait@vch.ca)
- In Phase II they will continue working toward a collaborative review model(s) and maximal reciprocity agreements between organizations. As well, working groups will be formed to address key areas such as Education & Best Practices and Forms & Templates.

Changes Affecting Clinical Research

- Redrafted chapters on Clinical Trials, Human Biological Materials, and Human Genetic Research
  - Clinical Trial Registration: "All clinical trials shall be registered (Article 11.3)."
  - Monitoring Safety and Reporting New Information (Articles 11.7 -11.9)
  - Financial conflict of interest (Article 11.10)
  - There is a much longer discussion of the dissemination of results (Article 11.12)
  - Incidental Genetic Findings (13.2)

- Incidental Findings: “Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.”(TCPS 2 3.4)
  - Implication: “When material incidental findings are likely, researchers should develop a plan…”
- Research Directives: “Where individuals have signed a research directive indicating their preference about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process.” (TCPS 3.11)

Chapter on Aboriginal Research

- Expanded from 4 to 28 pages
- Draft content subject to considerable criticism & debate
- Emphasis on engagement of community in study design, personnel, data analysis/interpretation
- Greater recognition of differing interests in communities (esp. those without voice in formal leadership)
- Recognizes ethical validity of research that critically examines conduct of public institutions or organizations or persons exercising authority over communities
- Emphasis on research that directly benefits/builds capacity in communities

Chapter on Qualitative Research

- Review not required for exploratory phase intended to discuss feasibility or design of research, establish research partnerships
- "Under a variety of circumstances signed written consent is not appropriate in qualitative research"
- Observation in natural/virtual environments where people have reasonable expectation of privacy may be approved without requiring researcher to obtain consent from individuals
- Recognizes acceptability of disclosing participant identity in some contexts
- In studies using emergent design researchers can provide REB with all available information to assist in review & approval of *general* procedure for data collection

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