

October 4, 2021

Interagency Panel on Research Ethics  
Secretariat on Responsible Conduct of Research  
Canadian Institutes of Health Research  
160 Elgin Street, 9th Floor  
Ottawa ON K1A 0W9  
Canada

Dear Panel,

Thank you for the opportunity to respond to the proposed changes to the TCPS 2. Our board reviews research at Public Health Ontario and public health units across Ontario. Our reviews often focus how to manage risks to populations and communities in addition to risks to individuals. Because of our unique perspective we have highlighted issues that we anticipate will need to be clarified to best support public health research.

**Province:** Ontario

**Affiliation:** Public Health Ontario

**Capacity in which comments are submitted:** Ethics Administration and REB Chair

**Main Discipline:** Public Health evidence generating activities including research, program evaluation, surveillance, and quality improvement.

### **The Review of Multi-Jurisdictional Research**

We commend the Panel for prioritizing harmonized review processes. There are three areas of concern that we want to bring to the Panel's attention:

1. **Local Boards:** More guidance is needed to ensure that Indigenous community and regional boards, and other community-based REBs, will be deliberately included in the new review process. There may be a risk that a strict centralizing of the review to the primary REB will create gaps around the local context which may normally be managed by a local review. Section 3.3 of the proposed guidance document states that a local REB may advise the REB of record to reconsider its decision in light of local circumstances (lines 108-111). However, gathering feedback from community REBs only after the fact of the initial review could replicate, or signify, an imbalance of power between institutes and communities as described in TCPS 2 Chapter 9B.

We suggest for projects that fall under the auspices of Indigenous REBs, or other REBs that represent unique groups who could be vulnerable in the context of research participation, that the guidelines emphasize treating community boards as partners in the initial review process. This can assist both boards if the primary REB can proceed with more confidence in their review and the community REB is better equipped to either approve the protocol right away or provide feedback for improvements. We suggest including some additional guidance regarding engagement with Indigenous community boards:

- a. Early scoping of the project by the researcher should take into account any community-based REBs or similar bodies. The REB of record should be pro-active in ensuring community boards are consulted.
- b. Community boards should be included early in the review process to ensure that the REB of record incorporates community-based REB perspectives in the initial review. REBs of record should also work to avoid creating a burden for the community REB in the consultation process.

Community autonomy and capacity building, including capacity building in the ethics review process, should be a priority even if an institutional REB is responsible for the primary review. Allowing more autonomy for community boards and encouraging early engagement can help research progress while balancing risks to communities.

2. **Community Engagement:** For research projects that involve communities, the harmonized review will place a greater responsibility on the REB of record to ensure that local contexts are respected and appropriate community engagement takes place. This will require collaboration with local REBs and other community stakeholders in earlier stages of the review process than the current model suggests. This can potentially be addressed by guidance for REBs and researchers to prioritize local considerations early in the review process.
3. **Comprehensive Coverage of Work at all Sites:** In our experience, where each site is responsible for different elements of a project, applications submitted by the Principal Investigator for approval by the primary REB sometimes lack a full description of the work to be completed at our site, particularly when that portion of the work is of minimal risk. In these situations, it is not possible to rely on the primary approval, as the local work was not considered in the review. We suggest that guidance be included to ensure that review and approval of multi-jurisdictional research sufficiently consider the work to be done at each site.

### **Broad Consent in Research**

The clarification for how to review broad consent processes provides useful guidance for reviewing projects that include this methodology. There are two gaps in regards to risks to communities and populations that we address below:

1. **Risks:** the risks listed in 5.3 are not extensive enough in the context of harms to populations and communities. A participant's data that is linked to their identity, or parts of their identity, can be used as evidence in studies about groups to which they belong. Whether this is where they live,

their ethnicity, or other unique traits, the risk of harms extends beyond the individual to their communities. Lines 96-105 describe the researcher's role in anticipating whether an individual seems to have a personal capacity to understand and absorb potential harms. We suggest that guidance include that the researcher has a wider concern for protecting communities or groups that may be harmed by misuse of the participant's data.

2. Incidental Findings: There is a gap in the guidance for managing incidental findings from future research that may be carried out by different researchers. Researchers should be directed to the TCPS guidance document for How to Address Material Incidental Findings for consideration in designing their broad consent process. Risks to communities should also be considered in evaluating risks of incidental findings.

Regards,



Nancy Ondrusek, PhD  
Director, Research and Ethics Services  
Public Health Ontario  
Adjunct Lecturer, Dalla Lana School of  
Public Health, University of Toronto  
Member, Joint Centre for Bioethics



Elizabeth Peter PhD, RN, FAAN  
Professor  
Lawrence S. Bloomberg Faculty of Nursing  
Member, Joint Centre for Bioethics  
Chair, Ethics Review Board, Public Health Ontario  
University of Toronto