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From: Bell Erin
Sent: Fri, 1 Oct 2021 09:46:18
To: secretariat (SRCR/SCRR)
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal
Attachments:
MultiJurisdictionReview_HiREBFeedback_2021OCT01.pdf

Dear members of the Panel on Research Ethics and the Secretariat on Responsible Conduct of Research,

Attached please find the feedback from the Hamilton Integrated Research Ethics Board (HiREB) regarding the proposed revised guidance on Ethics Review of Multijurisdictional Research.

Demographic information

Province or territory: Ontario

Affiliation: hospitals and university

Capacity in which you are submitting the comments: REB members and REB administration

Your main discipline: Biomedical and Health Sciences

Please do not hesitate to contact me should you have any questions or wish to discuss. We would welcome the opportunity to speak with you on this topic.

Sincerely,

Erin

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Erin Bell

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Please be advised that we are currently investigating reports of applications not auto-submitting as expected. Please see www.HiREB.ca for more information or contact our helpdesk at eREBHelpDesk@hhsc.ca

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HiREB
Hamilton Integrated Research Ethics Board

October 1, 2021

To: Tri-Agency Panel on Research Ethics and the Secretariat on Responsible Conduct of Research

Regarding: ETHICS REVIEW OF MULTIJURISDICTIONAL RESEARCH – PROPOSED REVISED GUIDANCE

The Hamilton Integrated Research Ethics Board (HiREB) has been in operation since 2013 and provides ethics review and ongoing oversight of health research on behalf of four separate legal entities: Hamilton Health Sciences Corporation, St. Joseph's Healthcare Hamilton, McMaster University and Niagara Health. HiREB fully supports streamlined approaches to research ethics review – in addition to providing a local multi-jurisdictional review, HiREB was an early adopter of Clinical Trials Ontario's Streamlined Research Ethics Review System.

Recognition by the Tri-Agency Panel on Research Ethics in the "confidence that a single, comprehensive ethics review of minimal risk studies should, in the vast majority of cases, be sufficient to provide the appropriate protection to participants" (lines 67-69) is a great step forward, as is recognition of existing multi-jurisdictional ethics review models. However, instead of mandating the use or supporting the expansion of models that work, the guidance appears to require adoption of single, pan-Canadian model of review for all multi-jurisdictional minimal risk research.

We request that the Panel re-issue this draft guidance following consultations with relevant organizations and REBs, prior to finalization. In addition, when revising the guidance we ask that the Panel:

1. Exempt Eligible Institutions (and correspondingly, their REBs) from the proposed model for studies reviewed using existing multi-jurisdictional ethics review models [such as Clinical Trials Ontario (CTO) and the Ontario Cancer Research Ethics Board (OCREB)]. While a pan-Canadian review model is a laudable goal, and one we support, there are practical and regulatory roadblocks; this should not prevent the local/ jurisdictional adoption of streamlined approaches.
2. Adopt a principle-based approach instead of mandating use of a single model; continue to support flexibility so that institutions (and correspondingly, their REBs) can chose the best approach for a given project.
3. Address underlying challenges related to what is considered to be research carried out within an institution's auspices and jurisdiction.

Details regarding specific concerns with the proposed guidance are outlined in the attached appendix.

We support the Panel's intent and the underlying principles. While we commend the Panel in recognizing the inherent challenges that exist in applying the TPCS 2 to multi-jurisdictional research, we do not endorse the proposed guidance – we feel it is setting back multi-jurisdictional review in Ontario.

Sincerely,

Dr. Mark Inman, MD, PhD.	Dr. Fred Spencer, MD	Ms. Erin Bell, M.Sc.
Chair, HiREB	Chair, HiREB	Manager, HiREB

APPENDIX 1: SPECIFIC CONCERNS WITH THE GUIDANCE

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1. The proposed model is more burdensome than the current multi-jurisdictional models and does not permit flexibility

The underlying principles appear to be that multiple ethics reviews of the same project do not add protection to participants, but do cause burdens and delays for researchers and prospective participants (lines 36-38). We support guidance that focuses on these principles, and agree that unnecessary requirements and perceived barriers should be removed from the TCPS 2 whenever possible.

However, the proposed process still requires multiple REBs to review the same project, while denying the local REBs the authority or ability to make changes based on that review (as we understand it, all changes must go back to the REB of Record). This is particularly problematic given that this model applies to minimal risk research, which should typically already be undergoing a delegated review (in keeping with the principles of proportionate review).

There are other mechanisms, outside of additional REB reviews, that can address 'local context' requirements, for example, the approaches used in current Ontario models. The 4-6 weeks of local review anticipated in the guidance would likely be unacceptable to researchers familiar with the efficiencies of the Ontario models.

In addition, the current proposal appears to limit multi-jurisdictional review to a single model to be used across Canada. This will limit REBs and institutions by preventing them from choosing models that work best for the study at hand. The current version of TCPS 2 allows for different multi-jurisdictional models, which seemingly will be set by the wayside with this new guidance.

HiREB reviews for both Eligible Institutions (as defined by the guidance) and ineligible institutions. Requiring Eligible Institutions to adopt this single model of review that is more burdensome than existing models and less flexible to project-specific needs could create a two-tiered system within our REB. Researchers may instead choose to conduct their projects under the auspices of the ineligible institutions when possible to avoid this proposed model. This is far from ideal.

We request that the Panel establish and adopt a principle–based approach (instead of mandating a single, specific model). Perceived barriers in the current TCPS 2 should be removed where possible and the underlying principles of the guidance expanded upon to provide greater flexibility to REBs and institutions.

2. The proposed model lacks infrastructure to support it

Of the multi-jurisdictional models referenced in the guidance, we believe all include some form of standardized infrastructure such as informed consent form(s) and other templates, standardized application forms, and/or electronic REB submission (eREB) systems.

There are a number of areas where this lack of infrastructure becomes particularly challenging in the proposed model including, for example:

- The need for clarity regarding roles and responsibilities, typically outlined in agreements or standardized processes. This is outlined in the current TCPS (Application of Article 8.1): "Whatever model is chosen, roles and responsibilities of all involved in the process should be defined and

agreed to at the outset." If the proposed model is to be mandated (which we do not endorse), there are a number of grey areas that should be supported by agreements or standardized processes. For example, requirements for ongoing review activities like major amendments, and whom participants should contact with ethical questions or complaints. These roles and responsibilities should be developed in consultation with stakeholders who have experienced the intricacies of multi-jurisdictional review.

- Outside of the established multi-jurisdictional models, it seems unlikely that local REB applications and eREB systems are set up to accommodate this specific model (ours is not) and will require revisions to existing systems or implementation of new ones. This new model will create considerable cost, and will not further harmonization.
- REBs have a range of administrative requirements, particularly when the REB also reviews research that is subject to other regulations (including Good Clinical Practices, US Federal Regulations, and jurisdictional privacy legislation to name a few). As a matter of practicality, some REBs have blended these to establish a minimum set of administrative requirements that include more than just TCPS 2. Not all REBs have their submission requirements and/or policies and procedures available to researchers at other institutions.

On a practical level, the lack of infrastructure is likely to result in the exchange of one type of administrative burden for another. Where the current single-site review process creates inefficiency through duplication of effort, the new model is perceived to create additional work.

3. The proposed process does not address the role of the institution

The policy includes examples of local circumstances that may warrant flagging to the REB of Record that include, for example, specific requirements of the local participants, local site, statutory requirements and differences in access to services (lines 112-120). These are all elements that could conceivably apply to all research conducted under an institution's auspices. It is not clear why these would require another REB to review the work done by the REB of Record to determine if it is acceptable locally.

The model also does not consider institutional requirements (for example, faith-based considerations like wording regarding family planning for research conducted at Catholic institutions) that may be incorporated in research documents like the informed consent form. How will these be addressed?

REBs and institutions work together to support the institution's role in ensuring the overall ethical conduct of research under its auspices. Some local REBs and their affiliated institution(s) have established communication pathways and expectations that support institutional notification of key events without the researcher taking action to report, pathways that have been included in some existing multi-jurisdictional review mechanisms. If the institution is not aware of these key events, and if different REBs provide ethics reviews for different studies, gaps may be created that impact participant protection.

Further, the proposed mechanism removes the institution's ability to determine whether the proposed approach to alternate review models is acceptable or whether to recognize an external REB as an REB of Record.

4. **Underlying challenges related to determining what constitutes research carried out within an institution's auspices and jurisdiction are not addressed**

Panel and Secretariat interpretations regarding what is considered to be research conducted under an institution's auspices and jurisdiction are noted as a contributing factor to the current situation ["Another factor is likely the broad interpretation from the Tri Agency Panel on Research Ethics and Secretariat on Responsible Conduct of Research of what constitutes research carried out within an institution's auspices and jurisdiction" (lines 33-35)], and yet the challenge remains unaddressed.

The TCPS 2 appears to recognize that some situations warrant an exception ["Should the institution determine that some situations warrant an exception to the requirement for REB review, the basis and conditions for case-by-case exceptions shall be clearly documented in the institutional policies." (Application of Article 6.1)], but broad interpretations provided by the Panel and Secretariat are often conservative and restrict the ability to apply reasonable exceptions.

Institutions (in consultation with their REBs) should have the authority to determine what is considered research under that institution's auspices and develop REB and institutional review requirements in accordance with the principles of proportionate review outlined in the TCPS 2.

The need for revisions to the TCPS 2 to address the existing challenges regarding what is considered 'research carried out within an institution's auspices and jurisdiction' is critical in light of this new guidance, as this is the crux for determining when multi-jurisdiction review models apply.