

Archived: Friday, October 29, 2021 4:37:45 PM

From: [Samantha Drover](#)

Sent: Mon, 4 Oct 2021 14:11:57

To: secretariat (SRCR/SCRR)

Cc: Susan Marlin; Richard Carpentier; Thierry Lacaze-Masmonteil

Subject: TCPS 2 CONSULTATION

Sensitivity: Normal

Attachments:

[CHEER_Response_TCPS2_ProposedRevisedGuidance_2021-10-04_Signed.pdf](#) 

*****Caution – email originated from outside of CIHR. Read the warning below / Attention – Ce courriel provient de l'extérieur des IRSC. Voir la mise en garde ci-dessous*****

Dear Members of the Secretariat on Responsible Conduct of Research,

Please find attached comments on the TCPS 2 "*Ethics Review of Multijurisdictional Research – Proposed Revised Guidance*". These comments are respectfully submitted by the Principal Investigators (Susan Marlin, Richard Carpentier, and Thierry Lacaze-Masmonteil, cc'd) and Project Manager (Samantha Drover) of [The Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research \(CHEER\)](#) on behalf of the CHEER project.

Below are the requested demographic details:

1. **Province or territory:** cross-Canada
2. **Affiliation:** Other: [The Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research \(CHEER\)](#), a Canada-wide CIHR-funded initiative to streamline research ethics review for child health research
3. **Capacity in which you are submitting the comments:** Representative of a group or organization (CHEER)
4. **Your main discipline:** Interdisciplinary (Biomedical, Health Sciences, and other: Research Ethics)

Thank you very much for the opportunity to provide feedback on this proposed revised guidance,

Samantha Drover

Samantha Drover, PhD

Project Manager, CHEER [_____](#)

613-533-6000 x 79480



This email originated from outside of CIHR. **Do not click links or open attachments unless you recognize the sender and believe the content is safe.** For more information, please visit [How to Identify Phishing emails](#) on the CIHR Intranet.

Ce courriel provient de l'extérieur des IRSC. **Ne cliquez pas sur les liens et n'ouvrez pas les pièces jointes, à moins de connaître l'expéditeur et croire que le contenu est sécuritaire.** Pour de plus amples renseignements, veuillez consulter [Comment identifier des courriels d'hameçonnages](#) dans l'intranet des IRSC.

TCPS 2 Consultation: Ethics Review of Multijurisdictional Research – Proposed Revised Guidance

The [Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research \(CHEER\)](#) is a 5-year (2020-2025) CIHR-funded initiative to streamline the research ethics review of child health studies across Canada, with the goal of working towards a single REB review for multi-site multijurisdictional studies. As such, we have a vested interest in the TCPS2 *Ethics Review of Multijurisdictional Research—Proposed Revised Guidance* and are grateful for this opportunity to provide feedback.

CHEER's directive hails from an operating grant, funded by the CIHR Institute of Human Development, Child and Youth Health (CIHR-IHDCYH) and the CIHR Institute of Genetics (CIHR-IG), with the explicit objective to “*establish a multi-province streamlined ethics review process for multi-site studies with the goal of achieving a single ethics review for pediatric research studies.*”¹ In service of this mandate, we have assembled a multidiscipline, cross-Canada team of 35 co-investigators and collaborators representing all regions of the country and garnered the support of 16 pediatric hospitals, research institutes and research intensive networks across the country. The CHEER Project also engages 21 REBs across Canada via the CHEER REB Advisory Committee, and involves multiple organizations concerned with streamlining research ethics review such as Health Canada, the Ministère de la Santé et des Services sociaux of Québec, Children's Healthcare Canada, and the Newfoundland and Labrador Health Research Ethics Authority.

Since receiving funding in April 2020, the pan-Canadian CHEER collaborative, including child health researchers, REB members, research ethics specialists, patients and advocates, legal experts, educational researchers, and physicians, among other experts have worked towards tackling exactly the challenge outlined in the *Proposed Revised Guidance*. Given our common goal and the fact that our initiative is funded by a targeted CIHR grant on the same topic, we were disappointed that the CHEER collaboration was not consulted on the *TCPS 2 Ethics Review of Multijurisdictional Research – Proposed Revised Guidance* before it was issued. Although the seemingly simplistic approach outlined in the proposed guidance may be workable in limited circumstances, in many circumstances it will not be. The publication of this draft guidance at this time, without due consultation and consideration prior, has the potential to set back efforts to build consensus and common and efficient processes across jurisdictions in Canada.

On behalf of CHEER, we would like to share our concerns regarding the streamlining approach proposed in this *Revised Guidance*.

¹ Canadian Institutes of Health Research (2019). “*Promoting child health through a collaborative approach to streamlined ethics review*”. Operating Grant: Pediatric REB initiative. [Funding Opportunity Details]. <https://www.researchnet-recherchenet.ca/rnr16/vwOpprntnyDtIs.do?prog=3134&view=currentOpps&type=EXACT&resultCount=25&sort=program&next=1&all=1&masterList=true&printfriendly=true>

Concerns Regarding the Proposed Streamlining Approach

Our main concerns, on which we will elaborate over the course of this letter, can be summarized as follows:

1. The proposed revised guidance would constitute a step backwards and would result in more, not fewer, research ethics reviews for multijurisdictional studies.
2. Mandating local REB acknowledgements (which we believe may result in REB reviews) following the REB of record review would prolong times to study start-up, reducing Canada's capacity for health research.
3. The cross-Canada legislative environment is not currently structured to effectively and efficiently implement the review model proposed in the revised guidance.
4. Trust among REBs is crucial for an effective streamlined process but having multiple REBs 'review' the REB of record review would likely not foster such trust.

First, the revised guidance will constitute a step backwards for provinces and territories that already can accept a research ethics review outside their jurisdiction. For example, an institution in Ontario can currently accept the research ethics review of a REB in Manitoba without an extra local REB review or acknowledgement. In this context, mandating the extra step of a local REB acknowledgement would be a step away from a streamlined process. Essentially, the proposed approach to streamlining multijurisdictional research ethics review will result in more, rather than fewer, research ethics reviews (or 'acknowledgements') than necessary.

Second, timeliness to study start-up is an important factor contributing to Canada's attractiveness as a locale for multi-site health research studies. The proposed revised guidance may prolong the time to study start-up. If, following the REB of record research ethics approval, each local site reviews and potentially raises additional ethical considerations for review, the timeline to study start-up may be delayed by weeks, if not months. With this approach, Canada's capacity for health research will lag behind that of numerous other countries that have adopted a single research ethics review process.

Third, given the varied capacity for accepting research ethics reviews from other jurisdictions, a flexible research ethics review model may help minimize the number of reviews in the short term while also allowing for movement towards a more streamlined pan-Canadian process. For example, given the current legislative context and the existing TCPS2 guidance, a multijurisdictional study may minimize the number of research ethics reviews by adopting a pluralistic approach: sites that are able to accept the REB of record review may do so without additional review or acknowledgement; other sites may obtain research ethics review through a streamlined provincial process, whereas yet other sites may have a delegated or full local REB review. Engaging in the streamlined process to whatever extent possible will help build understandings among REBs and institutions, which will in turn promote further streamlining. There should be no more reviews than necessary; sites that need not conduct an extra review or acknowledgement of the REB of record review should not be mandated to do so.

Fourth, we agree with encouraging communication and promoting trust among REBs but have some concerns regarding the method described in the revised guidance:

“REBs are encouraged to communicate among themselves, as this may be a way to resolve informally some of the issues that may arise during the process of multijurisdictional assessment.” (Lines 130-132).

The above process may potentially constitute a form of collaborative review that could involve members from all local REBs. Setting aside the question of whether a collaborative approach to a pan-Canadian streamlined research ethics review is advisable, terms of engagement among REBs would need to be defined (as opposed to the proposed informal approach). In addition, we believe that trust among REBs across Canada is crucial for achieving a streamlined multijurisdictional research ethics review process. However, having the research ethics review of the REB of record reviewed by multiple local REBs may not positively reinforce trust, and may instead exacerbate regional differences that do not necessarily impact the quality of the research ethics review.

Finally, we turn to this assertion from the proposed revised guidance:

“The proposed guidance is based on 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).

We wholeheartedly agree that a single, comprehensive research ethics review can be sufficient to protect participants across jurisdictions. Yet, despite this claim, the proposed revised guidance suggests a model that relies not on a single REB of record review, but instead on a REB of record review followed by mandatory reviews at each local site.

Cross-Canada Legislative Considerations

Underscoring all our above concerns is the current legislative, insurance, and liability landscape as it pertains to accepting or conducting cross-jurisdictional research ethics reviews. Specifically, while some provinces and territories can currently accept research ethics reviews from REBs outside their jurisdiction, other jurisdictions have legislative and/or insurance and liability requirements that limits their ability to do so (see Appendix, Table 1 for a summary). We recognize that the proposed process of seeking local REB acknowledgement of the REB of record review may, in some cases, ‘bypass’ the above-described legislative, insurance, and liability barriers to conducting a single research ethics review across jurisdictions. However, this mode of bypassing barriers ultimately leaves each local REB with the responsibility of local research ethics oversight of the study:

“The expectation is that a single REB of record will conduct the ethics review. Its decision and reasons, along with the final study materials, would be available to the REBs of all sites for acknowledgement.” (Lines 82-84)

“If the local REB identifies a missed local circumstance, or a substantive missed issue, these should be flagged to the REB of record for consideration...Exceptionally, a local REB may advise

the REB of record to reconsider its decision in light of local circumstances or a substantive issue that has not been addressed” (Lines 90-91, 108-110)

Considering the goal and intent of this revised guidance, a crucial question to ask is: Does the proposed approach—having local REBs review and acknowledge the REB of record’s research ethics review—move us closer to the goal of a single research ethics review for multijurisdictional studies across Canada?

Some Recommendations for the Proposed Approach to Streamlining Research Ethics

Given our concerns and considerations, we believe that further cross-Canada consultation is required. In the meantime, we would like to take this opportunity to share our recommendations for streamlining research ethics review across Canada; these recommendations are based on CHEER’s ongoing consultation with researchers, REB members, patients and advocates, and other stakeholders from across the country.

As we are learning through the CHEER initiative, jurisdictional differences in systems, policies, and review models are meaningful hurdles to streamlining the research ethics review of multijurisdictional studies. As such, we propose that efforts to streamline research ethics review across Canada be couched within a clear infrastructure that incorporates agreements and well-defined review model options. With a clear structure in place supporting research ethics review streamlining, jurisdictions will not be left with existing solutions that may or may not be compatible.

Furthermore, the review model that Canada adopts for streamlining the research ethics review of multijurisdictional studies should aim for a *single* review that can be relied on and accepted by all jurisdictions. Establishing a set of common standards against which all participating REBs are qualified would foster mutual trust and facilitate the acceptance of a single research ethics review by multiple REBs across jurisdictions. We recognize that a single review for all Canadian jurisdictions is not currently feasible given existing legislative barriers, but we believe that our streamlining efforts will constitute positive steps towards such a model.

Finally, to bolster Canada’s capacity for impactful health research, it is imperative to not only streamline the research ethics review of minimal risk research but also that of greater than minimal risk studies. Accordingly, we suggest that the *TCPS2 Ethics Review of Multijurisdictional Research – Proposed Revised Guidance* should aim to streamline the research ethics review of *all* multi-jurisdictional research.

Conclusion

In conclusion, we once again would like to laud the goal of this proposed revised guidance: promoting the expeditious review of research while ensuring the safety and wellbeing of research participants is at the core of CHEER. Thank you for this opportunity to provide feedback on the *TCPS2 Ethics Review of Multijurisdictional Research – Proposed Revised Guidance*. We hope that you will take our concerns and recommendations into consideration.

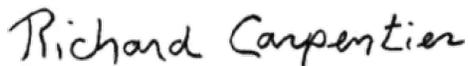
These comments are respectfully submitted by the CHEER Principal Investigators and Project Manager, on behalf of the CHEER project.



Susan Marlin
Nominated Principal Investigator, CHEER
President & CEO, Clinical Trials Ontario
Adjunct Lecturer, Queen's University



Dr. Thierry Lacaze-Masmonteil
Principal Investigator, CHEER
Professor, Department of Paediatrics, Cumming School of Medicine, University of Calgary
Scientific Director, MICYRN



Dr. Richard Carpentier
Principal Investigator, CHEER
Associate Professor, Department of Medicine, University of Sherbrooke
Chair, Montfort Hospital REB



Dr. Samantha Drover
Project Manager, CHEER

Appendix

Table 1. Cross-Canada Context for Streamlined Research Ethics Review

Province or Territory	Legislative Barriers & Other Considerations
British Columbia	Collaborative review model: Research Ethics BC uses a collaborative review model for studies involving multiple sites in the province.
Alberta	Alberta Health Information Act (HIA): Only designated REBs can review and approve health research in AB.
Saskatchewan	Saskatchewan Health Information Protection Act (HIPA) 29(1)(b): Health information for research purposes can only be disclosed for research that has been approved by a REB approved by the Minister ('order of council'). Note that REBs outside of SK may receive this designation.
Manitoba	Manitoba Personal Health Information Act (PHIA) Section 24 & Amendment to Article 59: REBs outside of MB may not be able to approve the use of public health information for research.
Ontario	
Quebec	<p>Article 21 of the Civil Code of Quebec: The research project must be approved and monitored by a competent research ethics committee. Such a committee is formed by the Minister of Health and Social Services or designated by that Minister from among existing research ethics committees; the composition and operating conditions of such a committee are determined by the Minister and published in the <i>Gazette officielle du Québec</i>.</p> <p>DARSSS (Direction des assurances du réseau de la santé et des services sociaux): The provincial insurance plan currently only allows for approving research within the QC system.</p> <p>MSSS Standard legal clauses for information and consent forms for clinical trials: Wording required in consent forms in QC.</p>
Nova Scotia	Indemnification: IWK cannot indemnify any party.
Newfoundland and Labrador	Health Research Ethics Authority Act (2011): All health research in NL must be reviewed by the provincial Health Research Ethics Board (HREB, overseen by the Health Research Ethics Authority).
Northwest Territories	Northwest Territories Health Information Act, Section 78: For multi-jurisdictional studies, approval from an extra-territorial REB may be sufficient.