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From: Susan Marlin

Sent: Mon, 4 Oct 2021 16:35:31

To: secretariat (SRCR/SCRR)

Cc: Matthew DAscanio; Marie Steele; Craig Prouk

Subject: TCPS2 Consultation - Research Ethics Review of Multijurisdictional Research

Sensitivity: Normal

Attachments:

Clinical Trials Ontario Response to TCPS2 Proposed Guidance- Research Ethics Review of Multijurisdictional Research.pdf 

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

Thank you for the opportunity to provide comments on the TCPS 2 “*Ethics Review of Multijurisdictional Research – Proposed Revised Guidance*”.

Below are the requested demographic details:

1. **Province or territory:** Ontario
2. **Affiliation:** Other: Provincial organization
3. **Capacity in which you are submitting the comments:** President & CEO, Clinical Trials Ontario
4. **Your main discipline:** Interdisciplinary (Biomedical, Health Sciences, and other: Research Ethics)

Yours sincerely,

Susan

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October 4, 2021

Tri-Council Panel on Research Ethics
Tri-Council Secretariat on Responsible Conduct of Research
Ottawa, Ontario
Submitted by email to: secretariat@srcr-scr.ca

Re: Response to TCPS2 Proposed Guidance: Ethics Review of Multijurisdictional Research

Thank you for the opportunity to respond to the proposed guidance regarding the research ethics review of multijurisdictional research. This response is supported by multiple organizations and institutions across Ontario. A list of organizations/individuals supporting this response is provided below.

The proposed guidance mandates that a single REB provide the initial research ethics review when multiple tri-council eligible institutions are involved in a research study that is of minimal risk. We appreciate this guidance has been issued with the very positive intent of expanding uptake of harmonized approaches to research ethics review. As acknowledged in the draft guidance by the Tri-Agency Panel “We are unaware of evidence that multiple ethics reviews provide commensurately greater protection for research participants. Many researchers believe that they may unnecessarily hinder the program of research.”

A policy change to support a single REB review for multi-site studies is strongly supported; however, as proposed the guidance could not be implemented broadly in Ontario. ***We request that this draft guidance be reconsidered and re-issued following consultations with relevant organizations and REBs.***

It should be noted that the current TCPS2 fully supports the streamlining of research ethics review and allows flexibility around the model institutions choose to follow. Although it may intend to, the guidance as proposed does not exempt existing streamlining systems, nor does it allow for flexibility in which streamlining model is implemented. The changes proposed would complicate advanced systems already in place and move us backwards in our efforts to ensure high-quality and efficient review models. *Even if studies reviewed through processes like the streamlined research ethics review system in Ontario (i.e., CTO STREAM) were exempted, this mandatory guidance will apply to studies conducted across Canada, impacting existing systems.*

Although the proposed guidance mandates a single REB provides the initial ethics review, it requires the REBs of all participating institutions to engage in the process as well—to identify local issues, to bring forward any ethical issues of concern and to acknowledge and accept the REB review conducted. This would mean local REBs would have the responsibility for acknowledging and essentially accepting the review conducted by another REB; however, they would not have authority beyond requesting reconsideration by the other REB. This is very different than the streamlined system we have implemented in Ontario. It would be difficult to implement locally and moves away from a single REB being involved in the review of multi-site studies.

In Ontario we have implemented a fully delegated single REB review model whereby only one REB, the REB of Record, reviews and approves multi-site research (see Appendix A for additional details). The participating institution formally delegates this responsibility to the REB of Record via a template delegation agreement, and local REBs are not involved. This fully delegated model of REB review of

multi-site studies was implemented by the Ontario Cancer Research Ethics Board (OCREB) in 2003, and advanced across all disease sites in Ontario with the implementation of CTO STREAM in 2014. It was collaboratively designed with the understanding and expectation that a single REB review would be conducted; local REBs would not be engaged in anyway in the review or acknowledgement of the study.

Key Challenges with the Draft Guidance

The proposed mandatory guidance would negatively impact the long-standing and efficient CTO system of delegated REB review. It would essentially move us backwards in Ontario for many reasons including the following:

- In addition to being mandatory, the proposed guidance details processes that many institutions and REBs in Ontario would be unable or unwilling to implement.
- The proposed guidance as written does not respect the right of institutions to determine the model of review acceptable for streamlining ethics review for multi-site studies, nor does it respect the responsibility of the institution (vs. the REB) to accept an external REB review
- The proposed guidance imposes additional and unnecessary responsibilities on local REBs in Ontario that have invested in, and fully supported, delegated REB of Record systems and processes
- For minimal risk studies we could no longer realize the efficiencies of a single REB being responsible for the ethical oversight of a multi-site study. The draft guidance indicates that after the initial REB review that each local REB would have **4 to 6 weeks** to conduct its review of materials and provide acknowledgement or request reconsideration. With the CTO system, after the province-wide REB review is completed, the REB of Record completes the site review in **8 days** on average.

We are sufficiently concerned about this draft guidance to request that it be re-issued following consultations. We wholeheartedly support and appreciate the efforts of the Panel and the Secretariat to address this important topic and hope to have the opportunity to contribute to a consultative process that includes due consideration of existing efforts across the country to streamline research ethics review.

Respectfully submitted by:

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Appendix A: Ontario's Streamlined Research Ethics Review System: CTO STREAM

CTO STREAM currently manages a single delegated REB review for over 1500 multi-site studies in Ontario. With 110 participating institutions and 19 fully qualified REBs, the system is broadly accepted and provides high-quality and efficient research ethics review. In this delegated single REB review model, one REB in the system provides ethics review and oversight to multiple participating institutions. Local REBs are not engaged in the review process of these multi-site studies.

The system was designed and built by the research and ethics review community in Ontario and considers applicable policy/regulation, best practices and leading tools developed across Canada. The system includes a single set of application forms, consent templates and collaboratively developed policies, procedures, and agreements. The web-based system includes communication, compliance audit and sign-off features. All participating REBs are reviewed and fully qualified through a robust qualification process. These components are all necessary to manage a single review efficiently and robustly across multiple institutions.

The system accepts any multi-site health research project and currently **manages over 340 minimal risk studies with near 60 participating institutions.**

CTO STREAM Delegated Review Process:

- An initial application for Research Ethics Review is submitted by an investigator from any of the 110 participating CTO sites/institutions in Ontario
- The application and study materials are routed through the system to one of the 19 fully qualified REBs in Ontario; this REB serves as the REB of Record
- Following review and approval by the REB of Record investigators at participating CTO sites across the province can submit a 'Centre' initial application for research ethics review, addressing local issues only
- The REB of Record reviews and approves the Centre application in an average of 8 days. The local REB has no role in the review of the study locally or otherwise; an institutional official approves the acceptance of the ethics review locally
- An REB of Record Delegation Agreement (a template agreement embedded in the system) is executed between the host institution for the REB of Record and the participating institutions
- After the initial review all items requiring review (e.g., amendments, annual renewals) are submitted to the system and managed efficiently in a similar manner