Archived: Friday, October 29, 2021 4:38:20 PM
From: Natascha Kozlowski
Sent: Mon, 4 Oct 2021 15:49:17
To: secretariat (SRCR/SCRR)
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal
Attachments:
OCREB Response to TCPS2 Consultation October 2021.pdf

Good Afternoon,

Attached, please find our comments on the proposed revisions to the review of multi-jurisdictional research. Thank you for providing the community the opportunity to comment.

Demographic information as requested:

Province or territory: Ontario

Affiliation: other

Capacity in which you are submitting the comments: REB administration

Your main discipline: Health Sciences

Sincerely,

Natascha

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Click here to view the 2019-20 OCREB Annual Report.

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October 3, 2021

Secretariat on Responsible Conduct of Research
350 Albert Street
Ottawa, ON K1A 1H5
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RE: Comments from the Ontario Cancer Research Ethics Board on the Proposed Revised Guidance to the TCPS2 Ethics Review of Multi-Jurisdictional Research

On behalf of the Ontario Cancer Research Ethics Board (OCREB), I am pleased for the opportunity to submit comments on the proposed revisions to the interpretation and implementation of the review of multi-jurisdictional research of the TCPS2 (2018).

OCREB provides high-quality, efficient ethics review and oversight of multi-centered cancer clinical trials in Ontario. OCREB is now in its 17th year of operation, serving as a centralized oncology-specific REB. Currently, OCREB has research ethical oversight for 640 cancer clinical trials conducted at 27 participating study centres representing a total of 1708 individual centre applications.

As a centralized REB, one of the participating study centres assumes the role of lead or "Provincial Applicant" and assumes responsibility for submitting all study-wide (provincial) materials, including all participant materials to the REB on behalf of the Ontario participating centres. Centre-specific applications are submitted once the study has been approved and centres adopt the provincially approved documents including all participant materials and apply only pre-approved administrative changes to their centre-specific forms including the centre consent forms. OCREB is delegated by each participating institution for the ethical oversight of the study and there is no involvement of each institutional (or local) REB in the approval or post-approval process.

The intent and philosophy of the proposed guidance aligns well with our support of a streamlined and harmonized approach for research ethics review. Particularly as we are also "…unaware of evidence that multiple ethics reviews provide commensurately greater protection for research participants. They do cause significant burdens and delays for researchers and prospective participants." It is for this precise reason that OCREB was established.

On behalf of OCREB, however, I would like to comment on the proposed guidance which has raised some concerns since it is not clear that it will allow REBs to move closer to having a streamlined approach to research ethics review or that it will lessen the timelines for the commencement of research at participating centres.

The proposed implementation appears to put the onus on the local REB to review the documents of the Board of Record and for the Board of Record to ensure that the local REB has acknowledged its review. It is important to note that the process described in the consultation indicates that no formal agreement between institutions is required for the review of minimal risk research. It is recognized that having the local REB acknowledge the

REB of Record review may evade the need for an agreement to be in place; however, it also leaves each local REB with the responsibility of local research ethics oversight of the study. While the revised guidance is proposed as mandatory only for minimal risk research at this stage, and optional for research that is greater than minimal risk, it is important to note that the level of review required for a study is determined by the REB of Record for the study once the ethics submission has been made to the REB. There is concern that it will be logistically challenging for REBs to implement different rules for minimal vs. more than minimal risk studies.

The proposed guidance puts an additional administrative burden on local REBs, researchers and the Board of Record. Considering the proposed timelines for local REBs to respond in the guidance document (three weeks for minimal risk and four to six weeks for more than minimal risk), it is not clear that this will streamline research ethics review. There are currently many examples of how Canadian REBs have streamlined their reviews using one of the three research ethics review models described in Chapter 8 of the TCPS2 (2018).

Finally, we appreciate that OCREB was referenced in the proposed revised guidance. However, this is our first consultation on the proposal.

We truly appreciate the Secretariat looking at ways to streamline research and provide guidance to Research Ethics Boards across Canada. We thank you for the opportunity to provide our comments. We also request that this draft guidance be reconsidered and re-issued following consultations with relevant organizations and REBs.

Sincerely,

Natascha Kozlowski, MPH
Executive Director, OCREB