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From: McMurray, Keitha
Sent: Wed, 22 Sep 2021 11:54:46
To: secretariat (SRCR/SCRR)
Cc: Murray, Dr. Brian (Neurology/Sleep)
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal
Attachments:
2021-09-22_Sunnybrook response to TCPS2 consultation_signed.pdf

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Dear Secretariat,

Please see attached Letter in response to the TCPS2 Consultation.

Demographics as requested:

1. Province: Ontario

2. Affiliation: Academic Health Sciences Centre / Hospital

3. Capacity: Institutional Administrator along with REB Chair

4. Discipline: Health Sciences/Clinical Research

Respectfully,

Keitha McMurray (she/her)

Executive Director, Research Integrity & Clinical Research Services

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September 22, 2021

To: The Panel on Research Ethics and the Secretariat on Responsible Conduct of Research

Subject: TCPS2 Proposed Guidance RE: Ethics Review of Multijurisdictional Research

Thank you to the Panel for seeking a public consultation and comments on four documents related to the interpretation and implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2018))*. Sunnybrook's feedback will be strictly focused on the proposed changes to the document on the "review of multijurisdictional research". All comments below are supported by the Sunnybrook Research Ethics Board (REB) as well as Sunnybrook as an institution eligible to receive Tri-Agency funding.

Sunnybrook has extensive experience in facilitating multi-institutional research. Sunnybrook cannot endorse the proposed revisions and will not be able to implement them if published as written. The paradoxical outcome of this proposal is that it will impair the longstanding processes that we have established through the Clinical Trials Ontario (CTO) model and will have not only a negative operational impact, but also significantly delay the process by which we can bring ethical research to participants.

The following are key points as to why Sunnybrook is not in favour of these revisions:

- The proposal is deemed mandatory and does not allow for flexibility for REBs/institutions, nor consider existing models (such as CTO) that are already working well. This will undo all of the work done over the last several years in the interest of streamlining multisite reviews.
- The proposed model still allows, and in fact seems to encourage, multiple REB reviews which is counter to the purpose of these revisions. This is the antithesis of a streamlined approach that the Panel is trying to achieve.
- REBs are overburdened in the current environment and this proposal would create more work (a) as a Board of Record that will receive local REB comments from all participating centres and (b) by requiring our REB to review studies that the institution has delegated to a Board of Record.
- The revisions have moved away from outlining the principles of multijurisdictional review and have outlined procedural requirements that will be significantly more burdensome and costly to implement. The infrastructure to support this proposal is lacking.
- Many institutions, ours included, will not allow for reliance on external REBs in the absence of agreements and a REB qualification process. This proposal fails to consider institutional responsibilities and how they intersect with the review of research.
- Allowing for local REB review in addition to assigning a Board of Record will delay the approval of studies and therefore delay access to research for our patients/participants.

We respectfully ask that the Panel seek further consultation on this chapter by directly consulting with stakeholders (e.g REBs, institutions, CTO etc.) Please note that CTO will be providing feedback to the Panel and Sunnybrook has added our name to their letter in support of their position which aligns with ours.

Thank you,

Keitha McMurray
Executive Director, Research Integrity & Clinical Research Services

Dr. Brian Murray
Chair, Sunnybrook Research Ethics Board