Archived: Friday, October 29, 2021 4:03:13 PM
From: McGrail, Kimberlyn
Sent: Mon, 4 Oct 2021 08:33:08
To: secretariat (SRCR/SCRR)
Cc: Longstaff, Holly [PHSA]
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal
Attachments:
TCPS response_COR-TF (BC) _Oct 3.pdf

Good morning:

\f0Please find attached a submission in response to the TCPS2 (2018) Proposed Revision 2021. This submission is being sent on behalf of the British Columbia COVID-19 Clinical Research Coordination Initiative (CRCI) Clinical Operations and Research Task Force (COR-TF)

1. Province or territory: British Columbia
2. Affiliation: Pan-BC network, coordinated out of UBC
3. Capacity in which you are submitting the comments: On behalf of a group / network
4. Your main discipline: Health Sciences, Behavioural Sciences and Social Sciences

Thank you.

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Proposed revisions to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS): Response from the British Columbia COVID-19 Clinical Research Coordination Initiative (CRCI) Clinical Operations and Research Task Force (COR-TF)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) is updated and modernized over time through a process that involves extensive public consultation across Canada. On June 15, 2021, a series of transformative revisions were proposed to the TCPS, which are undergoing public consultation until October 4, 2021. The revisions address the four themes below:

1. The mandatory single REB review of multi-jurisdictional minimal risk research in Canada;
2. The endorsement of broad consent in research and a proposed process for obtaining such consent properly;
3. The exemption from REB review for de-identified cell lines; and
4. Proposed changes to include new definitions of embryonic stem cells and totipotent stem cells and to the modification of the guidance and Articles that apply to research involving stem cells to include human totipotent stem cells.

We at the British Columbia COVID-19 Clinical Research Coordination Initiative (CRCI) Clinical Operations and Research Task Force (COR-TF) strongly endorse these proposed changes. We believe that if accepted, the revisions will be transformative to Canadian research both in terms of our ability to conduct world class research and attract new research opportunities for patients.

1. Proposed revised guidance for the ethics review of multi-jurisdictional research

While streamlined Research Ethics Board (REB) review has long been encouraged in Canada under TCPS, many institutions do not participate in any such efforts. To address this significant barrier to multi-site research in Canada, the proposed revisions make it mandatory for minimal risk multi-site research studies to undergo a single REB review in Canada. It is also suggested that while mandatory for minimal risk research, this guidance could also be extended on an optional basis to greater than minimal risk research studies as well.

The mandatory new guidance for all minimal risk research conducted under the auspices of multiple institutions includes:

- *"research conducted by researchers from more than one eligible institution;*
- *research conducted using the resources of more than one eligible institution;*
- *research involving researchers from one eligible institution and resources from another."*

This new mandate (if accepted after the public consultation period is closed) will have a major and transformative impact on Canadian research, but REBs will require time and resources to meet these new expectations. Canadian REBs will need to develop processes for acknowledging the approvals of other REBs and integrating them into existing local systems like RISe (the UBC online ethics system also used by many Health Authority-based researchers in BC) without creating negative impacts in other areas. Many of these platforms perform multiple functions for other research related activities such as grants and institutional approvals. However, these issues can be resolved over time especially if existing centralized infrastructures are utilised. We hope that researchers will be encouraged to use centralized processes where they exist, like the Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER) initiative to avoid unnecessary burdens on the researcher and local REBs. We also believe that these changes should be extended to above minimal risk research and that it should be clear that research with Indigenous communities is exempted from this new requirement.

Delays in the approvals by BC institutions for the conduct of multi-site research studies have a negative impact on research in BC. The COVID-19 pandemic has highlighted variations in practice for approval of research, but this is a long-standing issue. All BC-based public bodies, including Health Authorities, are

governed by the same legislation and policy, and interpretive and guidance documents and services are available from the Panel of Research Ethics, the Office of the Information & Privacy Commissioner for British Columbia[1] and the BC Ministry of Health[2]. Despite this, there are wide variations in the ways public bodies in BC apply the TCPS and relevant privacy legislation (the Freedom of Information and Protection of Privacy Act (FIPPA)). The challenges and inconsistencies are particularly acute in relation to obtaining access to Health Authority-governed data and biospecimens for research purposes, due to differing requirements related to data disclosure, different interpretations of when a privacy impact assessment is required, and different requirements for data transfer and related information sharing agreements. In other words, there is a tendency to combine and conflate ethics review with other review requirements. In some cases, these variations in privacy processes and interpretations attached to the REB reviews have led to entire Health Authorities being dropped from provincial studies. BC is well known to be one of the most frustrating provinces in which to conduct multi-site health research.

We believe that the TCPS changes proposed to multi-jurisdictional research in Canada will strengthen the protection of human research participants by creating consistency and accountability by endorsing a centralized REB process in Canada. The long-standing problems associated with REB in combination with privacy and other types of review for research will not solve themselves. We do not have the luxury of taking years to establish review processes as occurred with harmonization of multi-site ethics review, nor is it clear how a harmonized process could work across the entire country. The time to act is now. British Columbians cannot afford to lose any additional research opportunities. Our current processes are simply not working, and this is having a direct impact on patients.

A de-centralized approach to research privacy and ethics based on differing interpretations of law and policy will continue to result in exclusion of some patients in BC from vital provincial and/or multi-province research. When patients in some health authorities are not included in provincial or broader studies, they cannot benefit from the results of that research effectively making them therapeutic orphans. Yet the "right to share in scientific advancement and its benefits" is enshrined in the Universal Declaration of Human Rights[3]. This failure to uphold the right of all British Columbians to benefit from research is especially concerning under COVID-19 but also has important implications to other research situations. Further, continuing in this way is inefficient, as it duplicates privacy and REB work in a context where all are working under the same policy and legislative framework. The proposed changes to the TCPS will go some way to addressing these challenges.

2. Broad consent

Obtaining broad consent for future unspecified use of human data and biological materials in research is no longer controversial in the bioethics community and has generally been accepted as permissible for some time. As a result, the TCPS has proposed revisions to clarify its endorsement of broad consent for human data and biological materials and outlined the process for obtaining such consent properly.

We agree with this proposed revision, and also that it should be very clear whether subsequent uses are subject to REB review or not. We believe that broad consent should be both about "consent to good governance" and knowing if subsequent sharing will be subject to REB review or not. However, we are concerned about how the new TCPS interpretation regarding mandatory future, unspecified use of de-identified data relates to this new endorsement of broad consent. We believe that all these approaches to gathering consent are necessary including waivers of consent. There may be some rare cases when a late phase clinical trial may offer some direct benefit to participants and perhaps mandatory use of de-identified data may not be appropriate in these few cases. However, in most cases there is no real possibility of direct benefit, so we do not agree that requiring de-identified data for future unspecified use as a condition of research participation is coercive. Also, this new interpretation contradicts the Tri-Agency Research Data Management Policy which states that "*The agencies believe that research data*

collected through the use of public funds should be responsibly and securely managed and be, where ethical, legal and commercial obligations allow, available for reuse by others. To this end, the agencies support the FAIR (Findable, Accessible, Interoperable, and Reusable) guiding principles for research data management and stewardship." It is also the expectation of academic journals that authors make their data available to others to replicate their work to avoid scientific fraud. We think this interpretation if retained should be context specific and narrowed down to only rare late phase trials that offer the real possibility of direct benefit and should not be applied generally to all research.

3. Exemption from REB review for de-identified cell lines

We strongly endorse this new exemption as well as the exemption for identified human somatic cell lines that are already in the public domain since these additional reviews do little to protect the rights of research participants and are not a good use of REB and research resources.

4. Research involving totipotent stem cells

We also endorse the proposed changes to include new definitions of embryonic stem cells and Totipotent stem cells and to the modification of the guidance and Articles that apply to research involving stem cells to include human totipotent stem cells.

Final remarks

In closing, we at the COR-TF strongly endorse these proposed changes and believe that the failure to implement them will result in lost opportunities for patients and researchers to conduct and participate in impactful research.

References

[1] "Office of the Information & Privacy Commissioner for British Columbia. Access to Data for Health Research: Guidance Document; 2018." Accessed: Nov. 12, 2020. [Online]. Available: https://www.oipc.bc.ca/guidance-documents/2115.

[2] "BC Ministry of Health Policy Instrument. Access to Health Data for Research; 2018." Accessed: Nov. 12, 2020. [Online]. Available: https://www2.gov.bc.ca/assets/gov/health/conducting-health-research/data-access/access-to-health-data-for-research.pdf.

[3] B. M. Knoppers, J. R. Harris, I. Budin-Ljøsne, and E. S. Dove, "A human rights approach to an international code of conduct for genomic and clinical data sharing," *Hum. Genet.*, vol. 133, no. 7, pp. 895–903, 2014, doi: 10.1007/s00439-014-1432-6.