TCPS2 (2018) Proposed Revision 2021 – Consultation Response

Province: New Brunswick

Affiliation: Regional Health Authority

Submitting: Horizon Health Network Human Research Protection Program (HRPP)

Main discipline: Health Sciences, Interdisciplinary, Biomedical

The Horizon Health Network HRPP is an institution-wide program for protecting Horizon's human research participants and is currently the only accredited HRPP for a regional health authority in Canada. The HRPP consists of individuals, departments and committees with responsibilities for human research protection: Horizon executive leadership; the Offices of Research Services and Research Ethics; the Regional Director of Research Services; the Regional Director of Ethics Services; the members of the Research Ethics Board; staff with assigned responsibilities for HRPP operations; investigators; research staff; and others.

Thank you for the opportunity to respond to the proposed guidance posted on the Panel for Research Ethics' website for public comment on June 15, 2021. Members of our HRPP reviewed the proposed *Review of Multi-jurisdictional Research* and we respectfully submit the following comments for consideration.

The review of multi-jurisdictional research

Section	Comment
3.3 The REB of record is the research ethics board with authority to conduct the review.	We encourage a streamlined approach to ethics review however, the proposed model does not consider alternate review models where REB review and approval is one component of an institution's research oversight process. The proposed guidance assumes that REB review and approval is the only requirement necessary to initiate a study at a site which is not how all model's function. For example, at our site, all submitted research projects are subject to regulatory and methodology review before they are released to the REB. Pre REB review is necessary to ensure privacy considerations, proposed study methods, and research training requirements are reviewed and that appropriate resources to conduct the study are in place.

	We would also like to ensure that the process is clear that the REB of record determines the level of risk (not the applicant). What would be the process if the local REB deems a project at higher than minimal risk?
3.3 Acknowledgement by the local REBs of the REB of records decision	An example of an acknowledgement letter would be appreciated. It's unclear what elements an acceptable acknowledgment letter would include.
3.3 The flagging of issues by local REBs for the REB of record	Guidance would be appreciated on the process for communicating issues of concern to the Board of Record. For example, will sites with online submissions platforms manage multicenter studies through their platforms and create a file for each thereby facilitating communication?
3.4 Process for researchers and local REBs	We feel it's necessary to caution that researchers may "REB shop" for boards that may be perceived as being more supportive.
3.4 Paragraph 4 -Once the REB of record has completed its ethics review and made a decision, it is the researcher's responsibility to send that decision and associated final approved materials to the local REBs from all institutions involved in the research.	Please describe what is meant by sending the decision and associated final approved materials to the local REBs. Many institutions have online submission platforms where all research studies are submitted and tracked. We envision that this process would still be required as it would not be practical (or efficient) to manage multijurisdictional projects outside already established submission systems.

Final comment: With the recent release of Canadian standards for research, we envision that standards where requirements for research oversight are established, would instill trust among institutions and facilitate a harmonized multijurisdictional ethics review process.