4 October 2021

TCPS 2 CONSULTATION – Response to Guidance on the review of multi-jurisdictional research

We appreciate the willingness of the Panel on Research Ethics to provide guidance around a single board of record model for minimal risk research, and to providing an opportunity for input. While we are supportive of (and already participate in) a single board of record model for both minimal risk and more than minimal risk studies, we believe that the following issues have not been sufficiently described or considered:

1. There are two essential components of successful single board of record models: inter-institutional reliance/participation agreements and distinct delegation of review/approval responsibilities to a single Board of Record.

   The success of CTO and OCREB has in part been because of having participation agreements in place which clearly outlines the responsibilities of all parties. The CTO process allows for institutional considerations to be handled by the Board of Record, where the local REB does not conduct any additional review.

   In the US, when one Institutional Review Board (IRB) relies on the review of another IRB, this arrangement is documented through an IRB Reliance Agreement in accordance with 45 CFR §46.103 and §46.114. The reliance agreement outlines the responsibilities of each party and delegates review authority to the IRB of record. In order for one IRB to serve as the single Institutional Review Board (sIRB), reliance agreements must be executed between the sIRB and each other site relying on the sIRB.

   At minimum a clarification of the roles and responsibilities of each party should be included in the TCPS2 guidance. Additionally a sample template could be developed which could serve as a starting point by which all parties can agree to.

2. No consideration has been given to the differing legislation and privacy requirements that are currently in place at provincial and territorial levels. These issues have been raised repeatedly over the last 15 years as a major barrier to harmonization of ethics review in Canada. We suggest explicitly stating that for inter-provincial research, the Board of record would be responsible for ensuring that research is conducted in accordance with all relevant legislation in all the provinces the research is being conducted.

3. We are concerned that the guidance document does not sufficiently address local requirements/circumstances for multi-jurisdictional research. As one example, Unity Health is a Catholic institution and is required to uphold its Catholic missions and values in all research projects performed onsite or under the auspices of Unity Health. As such, we have specific requirements for research projects conducted at our site. Other institutions such as paediatric hospitals or hospitals focused on a specific patient population (e.g. rehab or mental health) may have other specific local requirements that would require special consideration. Many REBs external to these organizations would not have the knowledge or expertise to ensure that these local requirements are considered in the REB review process and upheld throughout the life of the project. To address this issue, we suggest that local Institutions should be informed of any

submission to a Board of record pertaining to proposed research to be conducted at the local institution. The guidance document states that researchers should provide institutions with complete study documentation; however, this information is sent to the local REB after the study was approved by the Board of record. We suggest that it would be much more efficient if the Institution was notified *before* a study was reviewed by the Board of record and given the opportunity to provide feedback prior to review by the Board of record.

4. The single board of record provision as outlined in this guidance document does not obviate the need for the REB of any participating institution to consider the study in some form. The guidance states that researchers "should provide institutions with complete study documentation along with evidence of the ethics approval from the REB of record, and the final version of the study application, as approved by that REB". However, the subsequent sentence then suggests that the local REB is responsible to determine whether there are local circumstances or substantive issues requiring further review by the REB of record. The onus is put on the local REB to acknowledge ethics approval, yet there is no direction on what would occur should further review be required.

5. The US mandate for sIRB is limited to only studies funded by the NIH. The proposed single board of record in Canada does not limit the requirement to just those studies funded by the Tri-Agencies. It should be an option available, but not a mandatory requirement for those studies that fall outside of the Tri-Agencies jurisdiction.

6. While the TCPS2 defines "minimal risk", it has been our experience that this has been interpreted differently by REBs across the country. Consider including guidance on how to approach and resolve this situation, should it arise. Requiring researchers to notify a local Institution of a protocol that will be reviewed by another Board of record may be one mechanism to ensure that both the Board of record and the participating Institution agree that a study is minimal risk prior to review.

7. No mention has been made regarding the review and approval of amendments, continuing review and adverse events. This is of particular concern to Unity Health since changes could be made that might conflict with our missions and values.

8. There should be some consideration on how to handle the requirement for ethics review where a Co-Investigator has no in-person contact or access to identifiable data.

9. Given our experience reviewing COVID-19 related protocols during the pandemic, we suggest that there should be a provision regarding research conducted during a publicly declared emergency to further reduce barriers to research relevant to the publicly declared emergency. While many of the features of the guidance document will reduce some barriers to minimal risk research, we suggest including a statement around non minimal risk research during a publicly declared emergency such as a pandemic. We suggest that an analogous process for multi-jurisdictional research be mandated for non-minimal risk research when a) there is a publicly declared emergency and b) when the research is relevant to the publicly declared emergency

(e.g. COVID research during the pandemic). One additional safeguard in this circumstance may be to require non minimal risk research to be approved by 2 Boards with relevant expertise prior to the approval being recognized by participating institutions. This change would remove barriers to research during a pandemic while still safeguarding research participant safety.

10. It should be made clear that research cannot start in a particular institution until the participating Institution has acknowledged the Board of Record's approval.

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