William Osler Health System

Wednesday, September 29, 2021

To: Panel on Research Ethics & Secretariat on Responsible Conduct of Research

RE: TCPS2 (2018) Proposed Revision – Consultation 2021

Please accept this letter as a response to the open call for public consultation on the proposed updates to the TCPS2 (2018). William Osler Health System (Osler) Research Ethics Board (REB) is supportive of the intention behind the proposed policy changes. Our enclosed feedback was generated in the spirit of providing enhancement and clarity for all stakeholders which will interact and implement the policy. In the context of a community based healthcare institutional REB, the proposed changes may pose challenges due to the unique community that we serve and partnerships which we have developed. Please find enclosed comments on the proposed revision to the TCPS2 (2018) for your consideration.

Broad Consent:

I. If/when a repository is shared with researchers beyond the initial investigator, many aspects of the initially stated consent may be unknown (as the guidance outlines). It would be helpful for the guidance to provide further considerations for aspects which may be unknown or change with the sharing of banked data/samples and further define governance (i.e. retention periods, storage requirements, who may have access). This may be helpful for both researchers generating broad consent forms, and REBs evaluating these.

II. Further, it is felt that given the ever-changing privacy landscape within each province/territory, there may be a need to define certain privacy standards for research in Canada. The guidance may benefit from general rules or examples of secure methods of sharing repositories or research materials. Many institutions have local policy requirements, however for institutions or organizations which do not, having guiding principles will assist in ensuring appropriate and secure transfer of the research material (in turn, facilitating meaningful privacy protections for research participants across Canada).

Ethics Review of Multi-jurisdictional Research:

I. The guidance suggests that the institutional REB of the lead PI or a selected REB with appropriate expertise would be selected as the Board of Record. However, many non-eligible institutions have adopted the TCPS2 and lead multi-centre research. The proposed guidance was unclear how situations would be handled where the lead PI is

based at an organization which is not an eligible institution, and the study involves multiple sites which are eligible organizations. Would the eligible organizations need to determine which of their sites would oversee the research for those particular institutions?

II. The Board of Record would presumably be responsible for review of safety reports such as local adverse events or unanticipated problems which arise during the course of research. Demographics across Canada vary widely. Institutional REBs have experience dealing with local participant populations, and in a community setting this longstanding experience may provide specific context to evaluating these types of safety reports. It is requested consideration be made to expanding the guidance to allow notification or consultation with the site of the adverse event or unanticipated problem upon initial report to the Board of Record.

III. In Ontario, it is not uncommon to find biomedical research being conducted by PIs that are cross appointed at different organizations (healthcare and academic). It seems there is potential for a lead PI to have their academic institutional REB review a biomedical research study which is being run at various healthcare institutions. Would it be reasonable to include provision in the guidance to require a biomedical REB act as the Board of Record for such studies to ensure appropriate expertise and oversight?

Thank you for your consideration of the above comments. Please contact our office at WOHSREB@williamoslerhs.ca should further clarification on the above points be required.

Sincerely,

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