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From: Erika Basile
Sent: Thu, 23 Sep 2021 12:25:40
To: secretariat (SRCR/SCRR)
Subject: TCPS 2 CONSULTATION - Response from Western University
Sensitivity: Normal
Attachments:
Western University REB response to PRE consultation_2021.pdf

Dear Panel on Research Ethics,

Please find attached Western University's response to the proposed guidance for public consultation, interpretation, and implementation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, (2018)).

Additional Information:

1. Ontario
2. Western University
3. Response comes from the Chairs of the Health Sciences (HS) and Non-Medical (NM) Research Ethics Board (REB) and the Director, Research Ethics and Compliance at Western University.
4. Disciplines: Western is a large University and our REBs are responsible for the ethical oversight for all research taking place at the University and its affiliated hospitals/research institutions/centers. The REBs sees a full gamut of research from Biomedical (from pediatrics to nonagenarians), Health Sciences, Behavioural Sciences, Engineering, Humanities, Interdisciplinary, Natural Sciences, Social Sciences, etc.

Sincerely,

Erika Basile,

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Western Research

Western University's Response to the proposed changes to the Panel on Research Ethics: Proposed Guidance for Public Consultation, Interpretation and implementation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2(2018))

Dear Panel on Research Ethics members,

In response to the proposed guidance for public consultation, interpretation, and implementation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, (2018)) we, the Chairs of the Health Sciences (HS) and Non-Medical (NM) Research Ethics Boards (REB) and the Director, Research Ethics and Compliance at Western University in London, ON, are grateful for this opportunity to provide feedback.

In general, we support the regulatory updates in the areas addressed in the proposal. Specifically, we applaud the clarifications provided about exemptions from REB review for research that relies exclusively on the re-use of de-identified human somatic cell lines. The guidelines are clearer, and we are happy to know that Western is already in compliance with these guidelines. We do, however, want to address specific concerns we have identified in the proposal for broad consent in research and the review of multi-jurisdictional research, respectfully.

A. Broad Consent in research

First, the intent of this proposal, as written, looks to only make it necessary for researchers to obtain a single consent for a data repository where they will then have unfettered freedom to do any research with that data, without explicit oversight from the REBs. For example, section 3 is not clear that secondary coded, anonymized, or identifiable data and/or biological materials still requires subsequent REB review per Articles 5.5A/B and 12.3A/B. At a minimum, we would request that you remove the words "In general" at the start of paragraph 2 of section 3 because then it would be much clearer that "The TCPS requires research involving stored data or human biological materials to undergo REB review…" If there are explicit exceptions to this requirement (e.g., research in other countries or research conducted under the auspices of institutions that are not eligible to manage Agency funds) this information can follow that updated statement.

Second, it is not clear why publicly available open data repositories like Open Science Framework (OSF - where subsequent REB review would not be needed per Article 2.2), or when repositories are housing information that was initially collected anonymously (which would not require subsequent review per Article 2.4) were not referenced in this section. Such a reference would add further clarification around the exceptions to the requirement for REB oversight.

Third, section 4.2 of the proposal states, "Participating in a specific and known research project must not be contingent on the participant consenting to unspecified research." If this is a requirement (i.e., it HAS to be optional for participants to agree to their data being shared in a repository such as OSF), this can pose challenges for open data purposes where the full data set is required for replicability, issues with futility when you don't have a complete data set, etc. It is not clear if this was considered when highlighting that this requirement must always be optional. We acknowledge that this optional

requirement may be appropriate for some repositories, but it becomes problematic if it is optional for other repositories such as clinical research data repositories where the data used, and results obtained may inform future health outcomes and treatments, particularly when the data will be sufficiently de-identified/anonymized.

B. Review of multi-jurisdictional research

We acknowledge the Panel on Research Ethics (PRE)'s good intention of wanting to streamline ethics reviews across the country while ensuring the safety and wellbeing of research participants; however, we would like to share some concerns regarding this proposed **mandatory** model. Although the principle of effectively streamlining the review process for both researchers and REBs is understood and supported, the operational requirements are too prescriptive and cause concern for feasibility and functionality when it comes to implementing the model.

First, this model does not seem to exempt institutions (and, correspondingly, their REBs) already using existing multi-jurisdictional ethics review models [such as Clinical Trials Ontario (CTO) and the Ontario Cancer Research Ethics Board (OCREB)] from following this proposed model. Furthermore, it also does not allow for flexibility so that institutions (and, correspondingly, their REBs) can choose which model for streamlining is implemented, instead of mandating a single model. The existing TCPS2 guidance that allows for more flexibility in the research ethics review model used should continue to be allowed. It should not be the role of PRE to mandate how it will be implemented.

Second, the proposed model lacks infrastructure to support it. This creates challenges that include a lack of clarity regarding roles and responsibilities, particularly in the absence of agreements, or standardized policies, and procedures:

- Without the requirement to have standardized application forms, consent forms, and an electronic REB management system, it is not clear how this model can be implemented. Furthermore, some REBs have administrative and institutional requirements (e.g., specific language) that vary and may not be readily available to other institutions and their REBs. Additionally, REBs and their administrative support structures vary greatly from institution to institution. This alone could create significant administrative issues when executing reviews and acknowledgements (as currently described in the guidance).

Third, the proposed guidance imposes additional and unnecessary responsibilities on local REBs that have invested in, and fully support, delegated REB of Record systems and processes. For minimal risk studies we could no longer realize the efficiencies of a single REB being responsible for the ethical oversight of a multi-site study because now the requirement is to have additional oversight from local REBs. This proposed model may be favorable to some institutions, but it is not beneficial to those REBs that have delegated review models such as with CTO and OCREB. There should be no more reviews than necessary; sites that need not conduct an extra review or acknowledgement of the REB of Record review should not be mandated to do so.

Fourth, the proposed process does not address the role of the institution. It does not respect the right of institutions to determine whether the proposed approach is acceptable, nor does it respect the responsibility of the institution (vs. the REB) to accept an external REB as the REB of Record.

Fifth, the proposed guidance fails to address the challenge of what constitutes research conducted under an institutional auspice. An institution may consider the local role peripheral on an external project (e.g., conceptual development, recruitment without consent, de-identified analysis, manuscript review, knowledge user not directly involved in the project, etc.) and this may not require local REB oversight. Institutions, in consultation with their REBs, should have the authority to determine what is considered research under their auspices and have REB and institutional review requirements in accordance with principles of proportionate review.

As noted above, we have significant concerns with the proposed mandatory model and cannot support it in its current form. We are requesting that the panel re-issue another draft only after further cross-Canada consultation with relevant stakeholders (including organizations (e.g., CTO and OCREB) and REB Chairs, REB operational staff). There are multiple examples of provincial level streamlining across Canada and these groups/organizations along with the institutions (and their corresponding REBs) that have implemented these models would provide a wealth of expertise and experience regarding the current context and how best to move forward with streamlining research ethics review.

In closing, we'd like to express our appreciation once again to PRE for the opportunity to comment on our understanding of the proposed updates and to suggest what we believe would be helpful clarifications/modifications prior to publishing these updates. We hope to receive feedback on our above concerns in due course. We also welcome the opportunity to engage in further consultation on these topics (and/or any others in the future).

Respectfully,

Dr. Philip Jones, HSREB Chair

Dr. Randal Graham, NMREB Chair

Dr. Emma Duerden, HSREB Vice Chair

Dr. Riley Hinson, NMREB Vice Chair

Ms. Erika Basile, Director Research Ethics and Compliance