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Response to TCPS2 Proposed Guidance_UHN REB.pdf

Hello,

As part of the public consultation on the proposed guidance regarding the four documents related to the interpretation and implementation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2018), please find attached our comments. These comments are being provided on behalf of the University Health Network Research Ethics Board. The board is part of a hospital in Ontario, whose main discipline is biomedical research.

Regards,

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moins de connaître l'expéditeur et croire que le contenu est sécuritaire. Pour de plus amples renseignements, veuillez consulter Comment identifier des courriels d'hameçonnages dans l’intranet des IRSC.

Response to TCPS2 Proposed Guidance

The Tri-Agency Panel on Research Ethics recently issued proposed guidance on four topics.

In response to the proposed guidance for public consultation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2, (2018)), the University Health Network Research Ethics Board Executive committee is thankful for this opportunity to provide feedback. In general, we are in support of the regulatory updates in the areas addressed in the proposal. We are appreciative for the clearer guidelines provided about exemptions from REB review for research that relies exclusively on the re-use of de-identified human somatic cell lines. We would like to take this opportunity to express concerns we have regarding the proposed changes to multijurisdictional research and broad consent in research.

1. Ethics review of multijurisdictional research

Although the intent and principle of this policy is applauded and the need to effectively streamline the review process for both researchers and REBs is understood and supported, the operational requirements are too prescriptive. There is concern for feasibility and functionality when it comes to implementing the model as described and within the mandated timeframe (as outlined in more detail below.)

1. Institutions and REBs using existing multi-jurisdictional ethics review models (eg. Clinical Trials Ontario, the Ontario Cancer Research Ethics Board) should be permitted to continue within the proposed guidance.
2. PRE should continue to support flexibility so that institutions can select the appropriate models and process that matches the needs of the institution and the studies they review, instead of mandating a single review mechanism and process across the country.
    a. The proposed model still requires multiple REBs to review the same project in some capacity
    b. The proposed model does not consider other mechanisms to address the local context requirements, in particular differences among provincial privacy regulations
3. Local REB applications and systems are not currently set up to support the proposed model, and Institutions and REBs will require time to develop processes, systems and frameworks to operationalize the proposed changes.
4. The proposed guidance does not take into consideration that one institution may deem the submission under review to be minimal risk while another institution may consider it to be above minimal risk or may not consider it to be research at all.
5. The proposed model removes the institutions ability to ensure that the Board reviewing the submission is qualified according to agreed upon standards
6. The proposed guidance should address the challenges that are faced when trying to understand what “research under the auspices” of an institution is.

i. The proposed guidance should allow Institutions to have the authority to determine what they consider to be under their auspices and subsequently create SOPs/Policies in accordance with the principles of proportionate review

2. **Broad Consent**

It is unclear if the intent of this section of the proposal, as written, is to only require researchers to obtain a single consent for a data repository, without explicit oversight from an REB for subsequent research.

It is unclear as to why publicly available open data repositories (where subsequent REB review would not be needed per Article 2.2), or when repositories are housing information that were 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.

It is noted that 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 mandatory requirement, this can pose challenges for open data purposes where the full data set is required for replicability.

We would like to express our sincere appreciation to the Panel on Research Ethics for recognizing the need to provide greater direction and guidance on these key elements and for the opportunity to comment and provide suggestions on the proposed updates prior to publishing these updates. We hope to receive feedback on our above thoughts in due course. We welcome the opportunity to engage in further consultation on these topics.