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From: Rachel Zand
Sent: Mon, 4 Oct 2021 14:47:18
To: secretariat (SRCR/SCRR)
Subject: TCPS2 CONSULTATION
Sensitivity: Normal
Attachments:
Response to TCPS2 consultation - Oct 2021.docx

Dear Secretariat,

Please see attached response to the following two documents for public consultation:

Review of multi-jurisdictional research

Broad consent

The demographic information is as follows:

1. Ontario
2. University of Toronto
3. Institutional submission – U of T
4. Applicable to all disciplines listed

Kind regards,

Rachel

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The University of Toronto is open, but due to COVID-19, staff in the Research Oversight and Compliance Office – Human Research Ethics Unit are working remotely to support operations as effectively as possible. Note that staff are not available to accept mail or courier deliveries. Please send items digitally or contact me to make alternative arrangements.

U of T COVID-19 Information

Research and Innovation COVID-19 Information

UNIVERSITY OF TORONTO

INSULIN 100 Celebrating a Century of Health Innovation

University of Toronto Response to Tri-Council Policy Statement documents for Public Consultation

Multi-jurisdictional research

Lines	Comment
General	We welcome the opportunity to discuss multi-jurisdictional research and recognize that the issues are complicated. At present, there is no national system for evaluating the quality of REB decision-making (or the consistency in their decision-making) and ensuring that they have the necessary tools, knowledge and resources to conduct reviews at an appropriate standard. There are several models that have worked that PRE should consider and build upon. In Ontario, the Toronto Academic Health Sciences Network (TAHSN) qualification system, through independent audit of policies and procedures, was created by the respective hospitals to evaluate standards prior to engaging in reciprocity agreements. This model further developed in the Clinical Trials Ontario (CTO) qualification process which has been working for several years. A national system, either led or at least overseen by PRE should be created, with involvement from nationally recognized stakeholders such as CTO. Only through an evaluation program that is built on stakeholder engagement, can a large-scale reciprocity system be workable. There needs to be discussions with institutions about the legal liability issues inherent in this proposed model. A single REB review system is complicated to initiate from both review and administrative perspectives and may create more problems than it solves. We strongly recommend that single REB review be introduced voluntarily, as a pilot program. PRE or the SRCR should be involved in studying the pilot to determine its efficiency and effectiveness. Only with evidence that it works well, should it be broadened in scope and possibly eventually considered to be made mandatory.
29-35	It would be helpful if the focus on reducing burden for REBs and researchers would include the obvious benefit of re-defining what "under the auspices" of an institution means. To reduce the burden, TCPS should exclude REB review for situations where the researcher is not directly involved in participant recruitment, interaction, intervention, or access to identifiable data. If REB review is required only when the researcher is directly involved in human research activities (recruitment, interaction, intervention, access to identifiable data), many studies would receive only REB review at one site. This would reduce burden for REBs, researchers and the institution, without requiring additional administrative processes.
41-46	"We are unaware of evidence" is not equivalent to conducting research to determine whether the quality of one review is significantly different from more than one. The US has required single IRB review since 2019, to mixed results. It

	would be prudent for PRE to be rigorous in its assessment of this model and in communicating its findings.
47-49	REBs often disagree as to whether a research activity reaches the threshold of above minimal risk. Requiring single REB review for minimal risk research but not above minimal risk will cause confusion and disagreements for REBs, particularly for those that do not often see the same disciplines, methods or populations and/or have different amounts of experience or resources. Please see comments above regarding concerns about a single REB review system without an accreditation or certification system.
56-74	This section underpins the rationale for mandatory single REB of multi-jurisdictional research. As such, it is particularly problematic, as several assumptions are made that are not true in practice. PRE equates receiving Tri-Agency funding as being TCPS-compliant and therefore there should be consistency in REB decision-making. While operationally true, quality of REB review is dependent on resources, training, experience and expertise. REBs may use the same ethical principles to review protocols; however, they apply them in relation to each other differently. While this section describes the model as "review by a single REB", delegated reviews are not reviewed by the full REB. Delegated reviews are typically conducted by the chair, member, and/or REB administrator; there may be as few as one pair of eyes on any given protocol. Minimal risk is not equivalent to no risk, and with larger studies involving more participants, the magnitude of risk increases. One knowledgeable, well-trained reviewer may be sufficient if the study is straightforward. However most multi-jurisdictional research that doesn't fall into the model of our first comment, is complicated. Delegated review, as currently conducted in most institutions in Canada, does not meet the rigour described in this section.
82-175	The process described is similar to the University of Toronto's Administrative Review process for research involving the TAHSN hospitals, whereby the University accepts and acknowledges TAHSN REB hospital approval for research that involves the University in a limited capacity – student on the project, funding administration, data or biospecimen analysis or storage at the University. Administrative Review requires a significant amount of time and resources to do effectively, with outstanding issues sent directly to the researchers who submit the protocols, not the REB of record. It is also based on a trusting relationship that the University has with the hospital REBs, based on years of communication with REB chairs and administrators, as well as knowing that <u>many have undergone a qualification process,</u> by which competencies have been evaluated and approved. To create a similar process for acknowledging REB approvals from any other institutional (or independent) REB is problematic on several fronts. First,

	extending Administrative Review to any external REB would be resource-laden for the online system, and for REB administration. As described in this proposed document, there would need to be communication between REB administrators, a system to enable "local review" that would focus on non-research ethics issues, with acknowledgement or concerns raised and addressed in a timely manner. REB administrators are already overburdened, and this reduction of "bureaucracy" for researchers would result in additional processes for administrators. While all REBs and REB offices try to maintain reasonable timelines for review, it is understood that most are overstretched with respect to volume of submissions and competing responsibilities. While it's recognized that the time frame of three weeks, as proposed, is a guideline, it is highly unlikely that most jurisdictions could keep to this timeline. Without a dedicated administrator to handle these requests, it is likely the review and acknowledgement piece would be of least importance in the office, and failure to provide comment, even when important, would happen often. Please see our general comments above. In addition, for minimal risk studies we need to remember that delegated reviews may involve only one reviewer. This means that ethical decisions on a multi-institutional research study may fall to only one individual, with all other REBs relying on their decision. If single REB review is required, PRE may need to reconsider delegated review procedures for multi-site research studies.

Broad Consent

Lines	Comment
16-22	We appreciate that PRE has recognized the need to separate informed consent for specific use vs. future use, as participants' decision processes must be separate and different for the two distinct uses.
43-63	We agree that custodians of data repositories and biobanks must be included as parties involved in the shared responsibility for protecting participants. For custodians that are also researchers, there is expected awareness of their responsibilities in protecting participants by requiring approval by an REB or equivalent ethics committee or process. Biobanks often have infrastructure for ethical requirements and similarly are aware of the need for approval. However, for data custodians who are not researchers, the knowledge, training or infrastructure may not be there. PRE should consider data custodians and librarians as parties who need TCPS training to effectively conduct their work and ensure that principles of broad consent are upheld.
70-78	Withdrawal may also nullify or challenge the scientific validity of the data, which should be a sufficient rationale for not providing withdrawal once consent is obtained. Withdrawal and/or reconsent should be available for data collected from children once they reach adulthood, unless the deposited data are de-identified.
167-190	While the list of points about the repository and its governance would be useful, it is unlikely most repositories, whether institutional or local, have this information readily available to researchers to provide. Is there a current system of oversight for repositories? Should there be? PRE should work with the Tri-Agency through the Research Data Management policy to ensure that institutions and repositories have the necessary governance to answer these questions.
191-203	Ongoing broad consent is a complicated issue. Whenever possible, data should be de-identified prior to deposit, therefore removing a requirement for ongoing broad consent. PRE should consider specific cases whereby a need for ongoing broad consent is required, as the exception, not the rule. As individuals generate data through many actions each and every day, it is important to normalize data collected through research as no more or less precious than data obtained otherwise. As researchers may use a combination of data sources – collected through research or not – we should not consider research participants as more important than other data subjects in terms of protecting privacy. One such exception would be research involving children, as they reach adulthood, as explained above.
General	The Broad Consent document is heavily skewed towards quantitative data and biospecimens. PRE should consider differences with respect to privacy, confidentiality and broad consent, to provide further guidance for researchers and custodians on deposit and reuse of qualitative data.