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From: Lori Ann Walker
Sent: Mon, 4 Oct 2021 18:55:29
To: secretariat (SRCR/SCRR)
Cc: Lori Ann Walker; Breb Chair; Angela Book; Dipanjan Chatterjee; Research Ethics Board
Subject: TCPS2 CONSULTATION
Sensitivity: Normal
Attachments:
TCPS2 consultation response 2021 Brock University.pdf

Dear Panel members,

The Brock University REB(s) would like to thank you for this opportunity to comment on the proposed changes to the TCPS2 (2018). You will find our comments attached. Please note that we restricted our comments to the areas of multijurisdictional research and broad consent as these are changes that will most impact our researchers.

Demographic information:

1. Province: Ontario
2. Affiliation: Brock University
3. Capacity: Research Ethics Board(s) and Office of Research Ethic
4. Discipline (panels): Social Science Research Ethics Board (SREB) and Health Science Research Board (HREB)

Thank you

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TCPS2 Public Consultation 2021 Response

Brock University

The review of multi-jurisdictional research

- It is our understanding that the intent of this document is a representation of what will be removed and what will be added to the current guidelines. A secondary document that outlines the changes as they would appear in the TCPS2 and how these changes might impact other areas of the TCPS2 would be helpful.
- Please consider that characterizing this change as a "single review" misrepresents the process given necessary reviews/acknowledgements at all sites appear to still be necessary. Also, further information is needed for multijurisdictional projects that include non-eligible institutions (U.S or other international partners). Presumably the single review model would not apply
- A revision to, or the deletion of the following language in section 3.2 is suggested:

  > *"This could be a member, or a research ethics administrator "with the appropriate experience, expertise and knowledge" (Art. 6.4, application)*

  It seems unnecessary to distinguish research ethics administrators with such experience and knowledge from board members given that Chapter 6, Article 6.4 already establishes,

  > "*Where research ethics administration staff have the requisite experience, expertise and knowledge comparable to what is expected of REB members, institutions may appoint them (based on the written policies and procedures of the institution) to serve as non-voting members on the REB."*

  It might be clearer to say that this task can be conducted by the chair or delegated to a board member(s) and that the REB should have written procedures for delegation in place.
- It appears that the REB of record will have already made its decision before study materials are made available at other site(s). This could be problematic if the other site(s) believes that unique circumstances specific to their site have been overlooked. Presumably, clearance for the project would have already been granted and articulated to the researchers by the REB of record. Yet the local site/other REB(s) may not acknowledge or respond for three weeks. It is not clear when the research can start. Would it start based on the decision of the REB of record, prior to local acknowledgment? It seems that if the local acknowledgement is required before research begins, the three week turn-around time (although understood to be maximum) could delay things. On the other hand, if the research starts with it and there are issues, would researchers be contacted to pause their research until the two (or more) boards came to a consensus?
- Clarification of process would be helpful in the event challenges/changes/disagreements arise following the board of record approval. How might disagreements between REBs be handled? If the REB of record cannot adequately address the local site's issues would the project just continue without local site?

Broad consent in research

- The concept of broad consent seems to most apply to biobanking. With growing focus on Research Data Management and data repositories that include but are not limited to biobanks, clarity is needed with regards to what types of data are intended for broad consent, (e.g., qualitative, quantitative, biological samples).
- A discussion of tiered consent may be a valuable as an option
- Further explanation is needed on whether and how this might impact secondary use of data review.