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Subject: TCPS 2 CONSULTATION
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Attachments:
THP REBs Consolidated Feedback on the 2021 Proposed Revisions to the TCPS 2.pdf

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Dear Secretariat,

My name is Jeff D'Souza, and I am the Research Ethics Board Coordinator at Trillium Health Partners in Mississauga. I am submitting the comments attached on behalf of the Trillium Health Partners' Research Ethics Board Members. We are a multi-discipline REB and review and approve research across various disciplines.

If you have any questions regarding the comments, or issues opening the attachment, please do let me know and I would be more than happy to assist in any way that I can.

Best,
Jeff

Jeff D'Souza, PhD

Research Ethics Board Coordinator

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Check out the IBH Annual Research Report: http://trilliumhealthpartners.ca/AR2019/Assets/IBH.html

Trillium Health Partners Research Ethics Board's Consolidated Feedback on the 2021 Proposed Revisions to the TCPS 2

1. Review of Multi-jurisdictional Research

- What is the definition of "multi-jurisdictional research"? Does this include research across national and provincial boundaries/? Privacy requirements and laws may differ significantly among countries, and many reviewers will not be familiar with laws, regulations, and standards of care/practice in the various jurisdictions.
- Without a standardized and more refined definition of "minimal risk," it is foreseeable that disagreements will arise among research ethics boards as to whether a particular study should be deemed minimal risk. THP's REB has in the past deemed a particular study to be minimal risk, where another REB has deemed the same study to be above minimal risk, and vice-versa. A clearer definition of minimal risk along with examples would help to address this challenge. What would happen if one site deemed a project minimal risk, and another site deemed a project above minimal risk?
- In section 3.2., it states that "ideally that consideration and acknowledgment would be done by a single individual at the local REB." Does "ideally" mean it's not mandatory? Relatedly, placing consideration and acknowledgement on a single individual may pose too large of a burden on one individual. Are there other instances where a single individual acts on behalf of the REB?
- How is the REB of record supposed to have considered local circumstances if they are not familiar with all participating sites?
- What happens if a local REB flags a concern to the Board of Record, but the Board of Record does not raise the concern or does not require the change to protocol?
- Could further details be provided in terms of how local REBs are to work with the Board of Record? Standardization and laying out specific procedures here would be helpful.
- We find the three week timeline for researchers to provide the necessary documents, and for local REBs to provide their acknowledgements fair and reasonable.
- Please clarify whether multi-site research requires an acknowledgement from all sites before the study can begin at any site?
- Do study sites receive communication back from the Board of Record if considerations are not implemented?
- We feel that being "unaware of evidence that multiple ethics reviews provide commensurately greater protection for research participants" requires further investigation into the matter. Has there been any research conducted into looking at the benefits of multiple ethics reviews providing greater protection for research participants?
- Even if there is a single review being conducted for projects taking place at multiple sites, there is still a need for contracts and material transfer agreements at each site. In our experience, these agreements and contracts may take additional time. Has this been explored as well?
- How is local context accounted for in multi-jurisdictional reviews? And, how do we ensure equity, inclusion and diversity are addressed in ways that represent the local community?
- Who ultimately gets to decide who the Board of Record is, and how do we ensure this proceeds in a fair, equitable, and transparent manner?
- Is there anyone tasked with overseeing the quality of the review to ensure reviews at other sites meet the threshold for rigour and thoroughness of an institution's own review process?

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- In the background section, please consider identifying/elucidating the "common set of ethical principles" to avoid confusion, and to provide greater clarity.
- Is the Board of Record for multi-jurisdictional research required to go through a Full Board review or does delegated review still suffice?
- Is there a formalized mechanism if REBs disagree on changes/recommendations? Perhaps an Appeals Board may be necessary, or if the study went through a Delegated Review, perhaps a Full Board Review may be required.
- The sentence "this guidance may also apply to research of more than minimal risk" is a bit unclear. Does the guidance apply to research above minimal risk or not?
- If no formal agreement between institutions is required to implement the process described above, how will researchers be held accountable? How will the process be known to key partners, members of the research community, and stakeholders?

2. Broad Consent in Research

- The new revisions provide a standardized set of considerations to help guide researchers, repositories and REBs, which also enhances accountability of REBs, researchers and repositories.
- It remains unclear what it means to inform participants of the "governance structure" of the repository. Can this be further explained and elaborated on?
- In the case of actionable incidental findings, it would be good if there was some mechanism to re-contact individuals who may benefit from follow up, especially with advances in technology and healthcare. In some cases, options to opt-out may be inappropriate depending on the study.
- It is important that researchers pay attention to the ways in which lack of access to internet and technology may limit a participants' ability to stay informed regarding their data
- We suggest changing the phrase "unexpected risk" to "risk" or "unlikely risk" because it's unclear how someone might go about noting unexpected risks if they are truly unexpected.
- It would be good to clarify that broad consent is about data and tissues, and does not come into play when there is direct contact with participants.
- Line 132 should specify whether "linking" would/should be done – and be explicit about the role of linking.
- It is important to ensure that broad consent is easily understandable for the potential participants
- Earlier in the document, it states that choosing not to participate in the broad consent aspects of the research should not influence a participant's ability to participate in the local/known project – this should be included in this section (P. 4 of 6; lines 141 to 155) as well, as we imagine researchers (and REB members) will use the bullets in this section as a checklist.
- Regarding the limits of withdrawing consent, researchers should justify why they believe withdrawal is impractical or impossible to REBs.
- It would be helpful in the section on information to include in broad consent to say something about providing information about the identifiability of data/tissue, especially when dealing with studies involving tissue which contains DNA, which could at least hypothetically be linked to a particular person or their twin in many cases.
- It should be made clear that there needs to be an REB-approved study in place to access the registry data and the registry should require REB approval even if the data is being used for secondary purposes.
- REB reviews or some type of safeguard needs to be in place before accessing data in a repository.
- We suggest adding "and to enquire about and exercise their rights about participating in the repository" to line 190 regarding who to contact at the repository for information. Including this will help to ensure that persons know how to withdraw their data/tissue if they wish to do so.
- We suggest introducing further measures to respect the autonomy of participants with compromised levels of autonomy or developing levels of autonomy; e.g., while a young child may

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not be able to consent, as the child grows older, they should be provided with the opportunity to do so.

- In the section entitled “The shared responsibility to protect participants”, it is unclear who has what responsibility in this process? What is the responsibility of a researcher vs. responsibility of the repository? “Shared responsibility” seems a bit vague and it might be better to clearly define which responsibilities belong to whom.
- It might be good for there to be a requirement (similar to the clinical trials registry) that all studies and/or project teams that access a repository be made known, and that information about the study be publicly posted on a website, for example. This will ensure that publicly accessible information (in terms of knowledge translation and ongoing consent) is available about how the data has been used. Then, REBs or participants can use that information to decide whether to use that registry in future, or withdraw their consent for future studies, based on their core values.
- There should be an annual review for each registry at their primary REB (including documentation re: what studies have accessed the registry during the previous year).
- It might be good to specify whether researchers have a responsibility to provide new data/findings derived from research completed using the repository back to the repository.
- Although ethical considerations are likely similar, this proposed section might consider drawing a distinction between broad consent as (1) “consent for primary use of data/tissue” (i.e., data/tissue collected perhaps as part of usual clinical care or specifically for the repository, but the consent is not linked to a particular study, but perhaps a program of research or even broader) and broad consent as (2) “consent to secondary use of data/tissue” (i.e., data/tissue collected as part of a particular study and then “saved” for use in future studies) – most often we think broad consent is being obtained as the latter (secondary use of data), but there are examples of studies where a registry is established that is not linked to a particular study.
- Cultural and language barriers should be taken into consideration with broad consent.
- We think it’s important for REBs and researchers to know their communities and identify potential risks of using data in studies under the auspices of broad consent. There should be a preloaded communication strategy or resource available (e.g. “who we serve” document) for populations that have unique needs and risks (e.g., being aware of populations we serve).

3. The Review of Research Involving Cell Lines

- It is unclear who is making the determinations that (a) the use of research involving cell lines is unlikely to reveal participants’ identity, (b) a particular re-use of somatic cell lines has low privacy concerns/risks, (c) a REB would not add any further protections for research participants, and (d) the study is unlikely to cause new harm to participants if this is not being determined by an REB
- The analysis in the background box seems focused primarily on consent and privacy, but does not mention other ethical issues related to the reuse of cell lines that might be important (e.g., the type of research, the intent/purpose, etc.)
- The proposed changes are welcome additions that hopefully decrease the administrative burden on researchers and promote research with minimal to no privacy risk to study participants from whom the cell lines were obtained.
- We also thought it would be helpful to, on the REB application form, have a section asking PIs to list the cell lines used and provide the consent terms attached to them -- it would likely be too onerous for the REB to seek this information on its own.
- It is unclear how researchers will be notified that anonymous data does not require REB review if such projects do not require REB review

4. Research Involving Totipotent Stem Cells

- The distinction and incorporation of human totipotent stem cells is a helpful, and timely change given the current research ecosystem in Canada.

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- In Article 12.20, it states that “copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information shall be provided to SCOC and the REB to examine and evaluate any potential or actual conflicts of interest and to ensure the right to publish in a timely manner without undue restriction.” REBs do not typically receive or review contracts or budgets, and so we were wondering what the rationale is for including this statement in this section.

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