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Dear Panel on Research Ethics,

Please find below comments for Consultation 2021 – TCPS2 (2018) from the University of Victoria.

Sincerely,

Sandra Gibbons, PhD.
Chair, Human Research Ethics Board

I. The Review of Multi-jurisdictional Research

Research Ethics BC (REBC) Member and BC harmonization

The University of Victoria (UVic) has been a partner institution on Research Ethics BC (REBC, formerly BC Ethics Harmonization Initiative) since 2009. Through REBC, UVic contributes to guidelines and practices for multi-jurisdictional research occurring in and between BC academic institutions and BC health authorities. As such, UVic comments specific to REBC and BC harmonization are included in the REBC response to this consultation.

UVic-specific observations and comments

The following are comments about multi-jurisdictional review from a UVic-only perspective:

As an REB at a post-secondary institutional that reviews mostly non-clinical research and increasingly, clinical research due to cross-provincial collaborations with health authorities and in the health sciences, we offer the following foundational observations.

Multi-jurisdictional research is a reality that the University of Victoria has been operationalizing since 2005 (e.g., University of Victoria-Island Health Research Ethics Sub-

Committee precursor to BC harmonization) and on a study-specific basis since 2007 (Canadian Longitudinal Study on Aging). Multi-jurisdictional review and multi-jurisdictional research have been, and continue to be, driven by factors such as funding program requirements, various granting agency requirements, cross institutional collaborations, and the university's strategic research plan. The proposed TCPS2 change comes very late to the REB environment such that we question its utility and benefit for the research communities in which we are situated.

The UVic REB notes that standard practices for multi-jurisdictional review do not exist on a national level yet, those that do exist, reflect individual institutions, regional institutional relationships or were designed and implemented for specific studies.

Given the timing of this consultation, it seems that the changes are aimed primarily at institutions/REBs not currently involved in a multi-jurisdictional initiative (agreements) and/or do not currently use in-house procedures to address multi-jurisdictional study, yet this is not explicit. Additionally, it is unclear whether the purpose of the TCPS2 change is to replace established multi-jurisdictional practices/initiatives (of which there are many in the country, as noted) with the suggested "model" or to augment or improve existing practices. The scope is also not stated. Is the focus on national studies (large scale Canada-wide studies)?

Proposed purpose and impact on institutions and REB offices

Not all institutions support their REBs to the same degree and many REB offices, regardless of size of their institutions or research portfolios, shoulder heavy workloads. In the current environment, the proposed "single REB review" from PRE is unwieldy. It relies heavily or exclusively on REB offices/staff to manage processes and exchanges of documents over the life of the project(s) *and* necessitates coordination of communication with researchers who may only be part of a single component or arm of a larger study. The REB staff inadvertently assume the role of defacto project managers for potentially an increasing number of studies. Researcher responsibility (and this importantly includes *teams of researchers*) for their multi-jurisdictional study has been critically omitted.

Institutions without initiatives or practices or those in the formative stages of developing strategies for multi-jurisdictional reviews would benefit more by learning about models or procedures (large and small) at other REBs (post-secondary-specific, hospital-specific).

The architecture of multi-jurisdictional research

Our observation is that, while not all multi-jurisdictional research is the same, the architecture of multi-jurisdictional usually follows one of the following formats (or combinations) regardless of scope (national study, regional study or dyad study with two institutions). We provide these examples to ground our comments:

1. *Single uniform protocol*: The researcher or team of researchers adhere to one research plan with a set of shared, uniform procedures. The researcher(s) is tasked with conducting one protocol (e.g., in cities, provinces or select locations). Minimal to no procedural variation.

2. *Interconnected arms/sites protocol*: Each site (an institution with an REB) may have a specific arm for a region or population. The arms may or may not overlap or relate to another arm. Data pooling /sharing and medium protocol variation between arms or sites are anticipated.

3. *Separate, discrete, emergent protocols*: The researcher or team of researchers individually designs and conducts their own specific protocol for, at or with, a specific location, community organization, Indigenous nations or group of participants etc. Data pooling/ sharing and high protocol variation are anticipated.

In-house practices used by UVic REB

Outside of REBC (BC harmonization) we follow additional multi-jurisdictional practices for streamlining and reducing REB duplication while maintaining proportionate review.

1. A UVic faculty member(s) partners with a non-BC investigator with REB approval from their home Canadian REB

   UVic researcher provides the approved REB protocol of the Canadian REB with their UVic ethics submission (online system). They explain the nature of their involvement, the architecture of the study and what activities they are responsible for/are involved in. UVic's "bridging" review focuses on UVic components and activities and uses the documents from the other REB as a basis for our review.

2. Communication with UVic researcher about a research team member from another Canadian institution

   When reviewing an application with the name of a listed research team member from another Canadian institution, we instruct the UVic researcher to inform their colleague to contact their home REB for instructions. It is hoped that their home REB will accept the UVic approval and protocol in a similar way as Example #1. UVic does not usually hear from the UVic researcher as to how the other REB handles the situation. On occasion, the UVic research informs us that the other REB uses a version of our bridging procedure.

3. External researchers

External researchers are individuals who are not partnering with a UVic researcher and have no connection to UVic. They are typically graduate students or faculty from other Canadian academic institutions who have obtained REB approval from their home institution's REB or they may be private researchers without an affiliation. They typically contact UVic ethics about recruiting UVic participants (students, staff or faculty) for minimal risk, low/no contact research means (e.g., via internal departmental offices with knowledge of criteria) for virtual research (most frequent) or single session in-person research. UVic REB receives the approved protocol and Certificate from the external researchers and uses these documents to conduct a local and administrative review. Private researchers (rarer situation) are instructed to provide a research protocol to our office.

Concluding thoughts and recommendations

In UVic's 15-year experience, multi-jurisdictional review must be nimble and should, when possible, draw on a repertoire of a practices. Practices for multi-jurisdictional best fit the architecture of a study and be driven by the specific REB and their institution. As the purpose of multi-jurisdictional review is to streamline and reduce duplication while protecting participants and communities, benefits and administrative responsibility ought to be borne by the key stakeholders: the researchers, REBs, the institution, teams of researchers. Participants, as well as communities and partners (host organizations, Indigenous communities outside of the REB structure) are also a critical element warranting further consideration by PRE.

In the event that the continued lack of access to multi-jurisdictional review models and/or REB practices continues to impact researchers in some institutions or types of institutions (academic vs. health/hospitals) PRE should consider a different approach. We recommend that PRE:

1) Reach out to multi-jurisdictional researchers and ethics boards about their practices, and potentially adjust the aims and scope of the current consultation (possibly outside of this consultation, as needed);
2) Encourage the sharing of robust and tested multi-jurisdictional initiatives, practices, models within the REB community (via webinars, CAREB conferences etc.) to support similar institutions and REBs in the development phase and/or refinement of current multi-jurisdictional practices. Support a sustained national conversation on sharing and enhancing multi-jurisdictional practices and models.

II. Proposed Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials

UVic does not have questions or concerns to raise for PRE.

III. The Review of Research Involving Cell Lines / Exemption from REB review for de-identified cell lines

The italicised text should be retained because it provides critical information for REBs without a separate clinical research ethics board or those REBs who do not routinely review research involving de-identified cell lines and would benefit from the discussion about "consent terms."

A discussion between the provenance of de-identified cell lines, specifically, those that are purchased from commercial vendors and those received from individual researchers should be included. Using cell lines received from other individual researchers could introduce ethical entailments that are specific to a study.

Research exempt from REB review and activities that are exempt (not considered research involving human participants) listed in the TCPS2 (2018) are covered in different chapters. We suggest that the index (only available on the PDF version) be updated to specify: a) the chapters/sections referencing what types of research in the TCPS2 are exempt from REB review*; b)* the chapters/sections referencing the activities that are exempt from REB review because the activities are not considered research with humans.

IV. Research Involving Totipotent Stem Cells

UVic does not questions or concerns to raise for PRE.