To: Secretariat, Panel on Research Ethics (PRE)

From: Heads of Applied Research – Research Ethics Boards (HAR-REB)

Re: Tri-council Policy Statement (TCPS) 2 Consultation

INTRODUCTION

The Heads of Applied Research – Research Ethics Boards (HAR-REB) Subcommittee Executive, which includes REB representatives from Ontario colleges, is hereby submitting comments on two of the four TCPS themes that are part of the current public consultation. These themes are: 1) the ethics review of multi-jurisdictional research and 2) the proposed guidance regarding broad consent for the storage and use of data and human biological materials.

The HAR-REB Executive is composed of eight members, including seven members from REB colleges. The comments herein do not preclude each college sending additional comments on the proposed revisions.

The HAR-REB Executive would like to take this opportunity to thank the PRE and the Secretariat for putting in place this consultation and for providing enough time to respond, considering the summer period and the heavy workload involved with the beginning of a new academic year taking place during a pandemic. This is greatly appreciated.

SPECIFIC COMMENTARY

Please find below comments on two of the four TCPS themes under review.

1) The Ethics Review of Multi-jurisdictional Research

Benefits

- Could make the process faster and easier for researchers
- Could mean fewer full reviews are needed
- Much the same as our current process for projects approved at another REB, except that we would be using other REBs' forms
- New deadline for review of previously reviewed research is 21 days, which is longer than our current 10-working day benchmark.
- New guidance would only be mandatory for minimal risk research (lines 4-5) but may also apply to research of more than minimal risk (line 7).

Drawbacks

- We would like to emphasize the following from Chapter 1, Section C, on how to apply the Policy: "In designing and conducting research, researchers and REB must be mindful of the perspective of the participant" might it be in social, economic, cultural or another context. The previous paragraph states: "This legal context for research involving humans is constantly evolving and varies from jurisdiction to jurisdiction." An example is the variety for the age of consent throughout Ontario institutions. This requirement must be taken into consideration.

- From some literature reviews, it was shown that the public is lacking confidence in government/public sector organizations and researchers. Such confidence is essential to the research endeavour. In addition, care must be taken to avoid repeating the NIH Clinical Review Committee (CRC) experience based solely on researchers who demonstrated that participant issues were not taken into consideration and who required the change from Clinical Review Committees to Institutional Review Boards.

- We note that examples provided on lines 18 to 27 are based on health or university settings, which do not take into consideration the experience of applied research at Ontario colleges.

- We question the REB of record competency considering the application to article 6.3, which says: "In defining the scope of the REBMs mandate, the institution shall clearly define the jurisdiction of the REB to cover a range of research consistent with relevant disciplinary competence and a manageable workload." This also concerns mixed research projects and multi- pluri- and interdisciplinary research.

- Are the reasons for REBs' choices leading to the statements on lines 28-30 coming from evidence-based data? We do not see such evidence in the documentation provided. Our experience is that there may be valuable reasons for doing so and need to be considered.

- On lines 36 – 40, mention is made that: "we are unaware of evidence that multiple ethics reviews provide commensurately greater protection for research participants." We would like to note that our experience is different, particularly in the fields of research-creation and the various applications of TCPS 2 (2018) by researchers and even some REBs. Similarly, REBs have on occasion disagreed with other REBs' characterization of the research as minimal risk.

- Within the various issues addressed in the proposal, one is the demonstration through evidence-based data (quantitative and qualitative) of the participants' perspective about research and researchers, which does not appear clearly in the document. We also noticed that the REB's role is minimized.

- One person would decide whether to accept the other REBs' decision, not the whole REB.

- Each REB's application forms are different. It makes it difficult to find the information when it isn't presented in the traditional format.

- Some application forms do not collect enough information to inform a decision about research ethics.

- Some REBs accept email assurances as proof of protocol changes. If the researchers document the corrections or changes in the application itself, how will receiving REBs know what the final protocol looks like? Will they receive the original plus a long record of email correspondence?

- The REB of record is asked to assess local issues REB to REB. This may require some education about local policies to the REB of record.

- Ethics applications are not reviewed until the applicant submits an approved Request for Permission for Access to Resources for Research (RPARR) to verify the expected resources are available to them. It often takes longer than 21 days to get both RPARR and the ethics review completed.

- In the past, some REBs have rejected applications that other REBs approved.

- Regarding liability concerns: It is essential to address the issue of which REB and which institution is ultimately responsible (ethically and legally) for what occurs at local sites. For example: Who provides support when data are subpoenaed if the home REB of the Principal Investigator is not the "REB of record"? This question applies to minimal as well as more that minimal risk projects.

- Regarding conflict of interest issues (real, potential, or perceived): How should they be dealt with?

- The proposal is applied to research held in other countries conducted by Canadian researchers. What about different issues that may be encountered in a context that may be very different ethically and legally as concerns the responsible conduct of research from the applicable requirements in Canada?

- Before going ahead with the proposal put to consultation, we propose to make mandatory the discussion between REBs, leaving to each one the final decision for a project. We recognize that this may not facilitate the researcher's life in that each context would have to be taken into consideration, but it may allow for existing situations where large centres are imposing their perspective on populations that may be quite different (e.g. large urban vs. smaller suburban).

- Finally, delays are often directly linked to resources that an REB may have available.

2) Proposed Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials

- We note that this document is referring to broad consent in English and to "consentement general" in French, which could be translated as blanket consent.

- We note that the document appears to be referring sometimes to broad consent and sometimes to blanket consent, which to our perspective is different and has different implications.

- The consent process is rooted in one of the core principles of this policy statement, namely, the respect for persons. "This requirement reflects the commitment that participation in research, including participation through the uses of one's data or biological materials, should be a matter of choice and that, to be meaningful, the choice must be informed. An informed choice is one that is based on as complete an understanding as is reasonably possible of the purpose of the research, what it entails, and its foreseeable risks and potential benefits, both to the participant and to

others." (Chapter 1). Is there any possibility then that the participant's consent could be co-opted to the researcher, opening the door to a possible paternalistic situation?

- In other words, is a broad or blanket consent a truly informed consent? There is no information supplied to support the reason for the use of one's data or biological materials, the risks and benefits that may be involved (e.g. the internationally known Nuu-Chah-Nulth's experience on the Vancouver Island, amongst other examples).

- The notion of consent is the same throughout a person's life and should be applied in the same way.

- We also note that the fiduciary concept is absent from the proposal even if used in such situations as Supreme Court decisions (e.g. McInerney vs. MacDonald) or in the management documents of several data or biobanks.

- This proposal provides a large decision space for researchers and those responsible for the storage of data and human biological materials, and downplay significantly the REB's role (e.g. the section on the shared responsibility to protect participants). How is this considered under the light of real, potential, and perceived conflicts of interests?

- As mentioned above, it is not clear how a broad or blanket consent could truly be informed.

- On a final point of consideration: How can benefits and risks be determined if a research project is unknown to interested/involved parties? How can a potential participant make an informed decision if no information is available? One way to respond would be to bring to the discussion an individual decision vs. the common good, which appears not to be the case in this document.

- Correspondingly, the following situations must be taken into consideration. Databanks and biobanks are in place for 20 years or more. It is important to consider the difference in possible benefits and risks that became apparent from a research context dated 20 years ago. At that time, there was no automated learning, no deep learning, almost no artificial intelligence, and no patient partnership initiatives. When CHIR and the Canada Research Chairs program were created (in 2000), replacing MRC, they brought new changes to life as they relate to research orientations. Additionally, the creation of organizations such as *De Code Genetics* highlights ethical issues related to the deposit of research data and the appearance of open science.

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