

Dear Panel and Secretariat,

While it is important to simplify ethics review for researchers, the proposed guidance on review of multijurisdictional research will complicate and potentially slow review for many of the applications that are reviewed by our REB. While the proposed guidance may be “...based on confidence that a single, comprehensive ethics review of minimal risk studies should, in the vast majority of cases, be sufficient to provide the appropriate protection to participants,” it misses the reality of local issues that are not readily known by researchers or a board of record.

We suggest some changes to clarify collaboration between REBs that will keep reviews going smoothly for researchers. Potential edits to the guidance are included below the text of this reply.

**1. Please highlight the need for REBs to review proposals collaboratively, in parallel.**

The current proposal appears to take us back to the serial process the new guidance is written to avoid, where the board of record reviews the study and local boards are asked to acknowledge the approval. If the local board identifies an issue with the study, an amendment is required, revisions made, and re-approved, slowing approval for researchers.

We have adopted harmonized ethics review in BC through Research Ethics BC (<https://www.bcahsn.ca/our-units/research-ethics-bc>) to facilitate collaborative review amongst boards before approval to avoid this conflict and provide researchers with one point of contact at the board of record. Adoption of such a harmonized review system across Canada would meet our dual goals of facilitating research and protecting participants.

**2. Please consider assigning initiation of collaborative review on the board of record, rather than the researcher.**

Ideally, a national harmonization system would be developed, similar to that in place in BC, to automate communication between boards and simplify the application process for researchers. Researchers are focused on their studies and rely on institutions to communicate with each other. With a list of REB contacts in Canada, preferably through a single email or phone number (e.g., [research\\_ethics@bcit.ca](mailto:research_ethics@bcit.ca)), the board of record can forward proposals to local boards and request acknowledgement or revisions before approval. A standard time limit (e.g., ten business days) can ensure that reviews and acknowledgements are collected and collated without significant delay. Where necessary, researchers can help facilitate communication between boards by making contact with the local boards, discussing the study, and confirming contact information is up to date.

**3. Please reiterate the importance of considering local issues in ethics review.**

As a polytechnic institution with a non-traditional blend of government and regulator oversight, as well as faculty, staff and students from all industries and walks of life, there is an interpersonal and multi-layered dynamic that is difficult for those outside the institution (and many within the institution) to appreciate. Recruitment of employees by managers or students by instructors creates coercion that prevents free consent. Knowledge of this structure and dynamic sits with the local board and most external (and some internal) researchers are unaware and often design studies without taking these into account.

**Prior approval by an external board of record sets up a second dynamic where the local board is placed in the uncomfortable position of raising these important concerns and slowing the review, in the face of a potentially more experienced and influential institution.** This dynamic occurs frequently during reviews at our institution where an employee is working towards a degree (PhD or Masters) at another institution and participants are recruited exclusively from their own department or school at BCIT. Issues that might be considered minor at some institutions—e.g., involvement of instructor, supervisor, gender questions on surveys, and arbitrary age restrictions on inclusion—loom large for many participants at our institution. Having more eyes on an application improves the research for both the researcher and the participant and should be encouraged.

Existing TCPS2 Chapter 8 does an excellent job of guiding researchers and institutions in the review of multijurisdictional research and we do not see the need for new proposed guidance, except to facilitate collaborative review by REBs in Canada before initial approval.

In particular, from 8.1: “Ethics review of the proposed research at each collaborating institution helps to ensure that local issues and values are taken into consideration. This approach may be particularly important, though often more challenging, when there are relevant social or cultural differences between the participating institutions. When several REBs consider the same proposal from their own institutional perspectives, they may reach different conclusions on one or more aspects of the proposed research, that reflect local issues and values. REBs may therefore wish to coordinate their ethics review of research projects requiring multiple REB involvement, including conducting their research ethics reviews in a timely manner and communicating any concerns that they may have with other REBs reviewing the same project. When multiple REBs are involved, the principal investigators should work with their REBs to formulate a strategy to address procedural inconsistencies or substantive disagreements that may arise among the participating REBs.

Where possible, researchers should provide their REBs with the name and contact information of the other REBs that will also review the project to facilitate direct communication between the REBs, and help resolve disagreements that may arise.”

From Article 8.2: “Sensitivity to context is a key issue in the application of the core principles of this Policy to the ethics review of research involving multiple institutions and/or REBs. Researchers should consider the alternative research ethics review models at the planning and design stage of their research, and should consult with their REBs to facilitate the selection and coordination of the appropriate review model. In choosing the appropriate research ethics review model, the researcher and the REB should pay attention to the research context and the characteristics of the populations targeted by the research. The final decision regarding the selection of the appropriate model is the responsibility of the principal REB.”

Articles 8.3 and 8.4 point out that human research should be reviewed by all institutions involved, including inside and outside Canada and conflicts resolved through collaboration.

Thank you for the opportunity to comment on the proposed guidance. We look forward to working with you in developing a more collaborative approach to ethical review of multijurisdictional research.

#### **Demographic information**

Province or territory: BC

Affiliation: Polytechnic

Capacity in which you are submitting the comments: REB chair

Your main discipline: No speciality

**Allison Kirschenmann, PhD** (*she/they*)

**Faculty, Basic Health Sciences**

**Chair, BCIT Research Ethics Board**

British Columbia Institute of Technology

3700 Willingdon Avenue, SW3-3090

Burnaby, B.C. V5G 3H2

Tel: 604-451-6917 or 1-800-663-6542 x6917

<https://www.bcit.ca/applied-research/>

I acknowledge that BCIT campuses are located on unceded traditional territories of the Coast Salish peoples, including the territories of the x<sup>w</sup>məθkwəy̓əm (Musqueam), Səlíl̓wətaʔ/Selilwitulh (Tseil-Waututh) and Skwxwú7mesh (Squamish) Nations. I work remotely from the traditional territory of the Qayqayt First Nation.

-----

Suggested edits should the guidance move forward:

## **3.1 What is the policy basis for a single review of multi-jurisdictional research?**

All institutions eligible to administer Agency funds must comply with the TCPS. Consequently, all researchers based at eligible institutions must apply a common set of ethical principles to the design and conduct of their research. Similarly, all REBs must review research based on those same common ethics principles and guidance. The driving force behind this guidance is the principle of a proportionate approach to research ethics review ([Chap.1, Sec. C](#)): “[T]he intention is to ensure adequate protection of participants...while reducing unnecessary impediments to, and facilitating the progress of, ethical research.”

~~A single REB~~ Review of minimal risk research should not compromise participant protection. Researchers are the first to consider participant protection as they design their research. That consideration must include how the research will affect participants at all contemplated sites. [Collaborative REB](#) review by ~~a single REB~~s affords a second opportunity for consideration of the ethical impact of the research on all participants, at all sites. ~~The proposed guidance is based on confidence that a single, comprehensive ethics review of minimal risk studies should, in the vast majority of cases, be sufficient to provide the appropriate protection to participants.~~

Through the Tri-Agency Framework: Responsible Conduct of Research (the [RCR Framework](#)), there is also a shared accountability mechanism for the responsible conduct of researchers, and the appropriate oversight of research by institutions. Taken together, the shared principles and shared accountability framework provide a sound basis on which institutions may accept the review of REBs at other eligible institutions, [but are cautioned to raise local issues with the board of record before allowing studies to commence at their institution.](#)

## 3.2 What is the scope of this guidance?

This guidance is mandatory for all minimal risk research conducted under the auspices of multiple institutions. This includes:

- research conducted by researchers from more than one eligible institution;
- research conducted using the resources of more than one eligible institution;
- research involving researchers from one eligible institution and resources from another.

The expectation is that a single REB of record will conduct ~~the an~~ ethics review [in collaboration with local REBs](#). ~~Its decision and reasons, along with t~~The final study materials, would ~~then~~ be available to the REBs of all sites, [for acknowledgment to consider prior to review](#). Ideally, that consideration and acknowledgment would be done by a single individual at the local REB. This could be a member, or a research ethics administrator “with the appropriate experience, expertise and knowledge” ([Art. 6.4, application](#))<sup>Footnote3</sup>. Both the researcher (research team) and the REB of record should have considered local circumstances (i.e. circumstances unique to the particular site, such as a specific participant demographic, language, culture not necessarily present at other sites) as part of the study design and the review, respectively. If the local REB identifies a missed local circumstance, or a substantive missed issue, these should be flagged to the REB of record for consideration [within ten business days of receipt](#). The intention is to keep the REB of record as the sole REB that can make changes to the terms of the ethics approval.

This guidance may also be extended to research that is more than minimal risk, in accordance with the policies of the local institution, or where mandated through a formal agreement or by law (see discussion in the final section).

## 3.3 Who is responsible for ethics review of minimal risk research involving multiple institutions?

The REB of record is the research ethics board with authority to conduct the review in collaboration with local boards. The REB of record has the responsibility for continuing ethics review. The REB of record must be from an eligible institution. The starting premise is that the REB of the (lead) principal investigator (PI) is usually the REB of record. However, it is possible for another REB to serve as the REB of record – for example, the one with the greatest expertise in the research topic, the one at the site closest to recruitment for the research, or with some similar important connection to the study. If the researcher(s) believe(s) that the REB of record should be from an institution other than that of the PI's institution, the onus would be on the PI to justify to their home REB why another REB would be better suited. They would also have to demonstrate that the other REB is willing to serve as the REB of record.

~~Normally, local REBs will acknowledge the decision of the REB of record. Exceptionally, a local REB may advise the REB of record to reconsider its decision in light of local circumstances or a substantive issue that had not been addressed.~~ Examples of local circumstances that might warrant flagging to the REB of record for reconsideration:

- Issues that only affect a locally recruited population (e.g. power of authority, language, culture);
- Issues imposed by unique characteristics of the local site (e.g. remoteness, limited access to needed resources to support local participants, issues specific to the local investigator);
- Statutory requirements (federal, provincial, or those of the country where the research is being conducted) that would have an impact on how the study was conducted;
- Substantial differences in access to services or standards of care normally followed at the local site.

### 3.4 Process for researchers and local REBs to follow

~~Researchers~~ The board of record should provide involved institutions with the complete study documentation, ~~along with evidence of the ethics approval from the REB of record, and the final version of the study application, as approved by that REB.~~ The designated individual at the local REB should consider these documents and determine whether there are local circumstances or substantive issues requiring further review by the REB of record. If there are not, the local REB should acknowledge the ethics approval by the host institution's REB.

If there are local issues, or substantive issues, the local REB must flag them for the REB of record. REBs are encouraged to communicate among themselves, as this may be a way to resolve informally some of the issues that may arise during the process of multijurisdictional assessment. If local REBs do raise substantive issues, even if only for participants at their site, the REB of record must address those in consultation with the REB that raised them.

Timelines should be established by the REB of record for researchers to provide the necessary documents, and for local REBs to provide their acknowledgement. In general, local REBs should complete their process and issue a letter or notice of acknowledgment within three weeks of receiving the complete package from the researcher board of record, ~~including the decision of the REB of record.~~ Footnote4

Once the REB of record has completed its ethics review and made a decision, ~~it is the researcher's responsibility to they should~~ send that decision and associated final approved materials to the local REBs from all institutions involved in the collaborative review research. ~~When the local REBs have provided their acknowledgment, the researcher is responsible for sending the local acknowledgments to the REB of record.~~ In addition, any further decisions by the REB of record during the course of the research must be communicated to the local REBs, and it is the responsibility of the researcher board of record to do so.

No formal agreement between institutions is required to implement the process described above.