Réseau de recherche sur les données de santé du Canada
Health Data Research Network Canada

TCPS2 (2018) Proposed Revision 2021 – Consultation Response

Region: Canada wide network

Affiliation: Universities, SPOR Units, provincial/territorial/federal government bodies

Submitting: on behalf of HDRN Canada

Main discipline: Health Sciences

As a network, the Health Data Research Network Canada (HDRN Canada) brings together provincial, territorial, and federal organizations which hold and manage data. HDRN Canada welcomes the Tri-Council's Panel on Research Ethics and the Secretariat on Responsible Conduct of Research guidance with respect to the interpretation and implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2018)).* HDRN Canada recognizes the need for access to multi-jurisdictional data that will allow researchers to address health challenges that cross boundaries, leading to advances that help develop innovative solutions and build Canada's international leadership in the health field.

Thank you for the opportunity to respond to the proposed documents as provided on the Tri-Council website (https://ethics.gc.ca/eng/consultations_2021.html). As a network we have specifically reviewed the proposed *Review of Multi-jurisdictional Research* and the *Broad Consent in Research* documents. We respectfully submit the following observations, comments, and recommendations for your consideration.

1. The review of multi-jurisdictional research

Document Reference	Comment/Recommendation
Not referenced - Indigenous data sovereignty	We note that there is no reference of Indigenous data sovereignty in this piece and recommend reference to Chapter 9 of the TCPS2 (2018) appear in all guidance documents to continue building understanding and respect with regards to research involving Indigenous peoples in Canada.
2. Background - successful harmonized and centralized initiatives currently in Canada that provide ethics review for multi-site research	Reference to these significant initiatives is welcomed and it is our recommendation that researchers should be encouraged to familiarize themselves with these bodies and use these infrastructures in place where available. Not only do these initiatives facilitate the review process but they can also provide invaluable subject area expertise. For example, the CHEER project for pediatric research provision of guidance on how to address adverse event reporting.

3.2 Scope of the guidance - proposed as mandatory only for minimal risk research	In recognition that REBs will need to extend time and resources to implement this guidance, we propose that the requirement extend beyond minimal risk where there are initiatives or formal agreements for centralized REBs. Many harmonized and centralized REB initiatives already in place in Canada are not limited to minimal risk research. These initiatives are the results of a great deal of effort and collaboration seeking to address the concerns of overworked REBs and the variation in approaches to project review/approval by different REBs leading some researchers to preferentially apply to given REBs. These initiatives have resulted in formal agreements that provide standards that can be emulated.
3.3 Responsibility for ethics review - a single REB of record will conduct the ethics review	While the need for multiple reviews will be eliminated, it must be acknowledged that the local REB review often serves as a platform used to fulfil other institutional requirements concerning grants, institutional reviews, etc. Accommodating for local processes will require adjustment.
3.3 Acknowledgement by the local REBs of the REB of records decision	A more streamlined approach to the acknowledgement process is recommended. While the recommendation to have the acknowledgement completed by an REB member or experienced administrator reduces the demand of the boards themselves, the number of administrative steps remain the same. What expectations are there for the content of the letter of 'acknowledgement'? What does 'acknowledgement' mean in this context? If it is about transparency or other, it should be said directly. **Recommendation:** Spot audits can be done time-to-time to ensure process is working correctly. **Recommendation**: A template should be provided for what is envisioned to be included in the letter of 'acknowledgment.'
3.3 The flagging of issues by local REBs for the REB of record	Clarification is required on the management of site-specific variations to multi-site protocols. How will differences be operationalized and captured? Ideally it would be within an existing centralized process/platform. Centralization can help avoid conflict when there are multiple REBS in an area - there is an inherent redundancy

	when different universities or boards are going over the same thing. **Recommendation:** Bodies with specific areas of expertise could lead/establish a centralized REB review panel for multi-region (multi-jurisdictional) research.
3.4 Process for researchers and local REBs	It must be acknowledged that when limited by their local REBs, researchers are going to go to boards that provide more supportive reviews and process, while perceived as "difficult' REBs will be avoided. **Recommendation**: Tri-Council Panel support the further development of and encourage researchers to use centralized REBs able to address these considerations such as the initiatives stated in Section 2, Paragraph 2. **Recommendation:** A network supporting research involving the secondary use of administrative data, HDRN Canada could step forward to establish a centralized body, including representation from all jurisdictions as a board of record for data intensive research.
3.4 Paragraph 4 - "If there are not, the local REB should acknowledge the ethics approval by the host institution's REB."	Is the reference to "host institution's REB" the REB of record?
3.4 Researcher's administrative responsibilities	The administrative process for the communication and document flow between multiple REBs does not facilitate or remove the current concerns expressed by researchers navigating multiple jurisdiction research work. Additionally, there may be institutional requirements and processes such as a privacy requirement at the local level beyond the review to be completed. These requirements will also need navigation when modifications may be required during the lifetime of the research project. **Recommendation**: Provision of a template directing researchers on where to begin and how to address these administrative requirements and resource demands.
3.4 Timelines and communication of completed decisions	Is the 3-week timeline realistic, considering researchers must facilitate all document distribution and the need to address considerations identified by the local REB?

	Is there a standard for the 'complete package' and who monitors the 'completeness' of a package? Although the guidance suggest work can begin where acknowledgements have been received, what if there are considerations identified that are in conflict?

Further consideration:

Secondary use of data carries unique risks: As identified in a growing body of literature (e.g., Hayward A.,et al., 2021[1], McLemore, M.R., 2021[2]) secondary use of data for research can do more harm to communities and systemically marginalized groups. There are also risks related to data security and privacy that many researchers REB members may not completely understand or have the knowledge to address (see HDRN recommendation to establish a body, including representatives from all jurisdictions of record for secondary use of data for research).

Provincial and Territorial (P/T) legislation: P/T legislation often includes review requirements and may not permit the assignment of a board of record outside of the local REB. For example, in NWT, the Health Information Act (HIA) specifically designates the Aurora College REC to review research that proposes to access the health information of NWT residents (HIA, Sections 67-83). Although provision is made for acceptance of REB approvals from other institutions this is not always the case. Are their best practices for such situations?

2. Broad consent in research

Document Reference	Comment/Recommendation
2. Broad consent being equated directly to consent for unspecific research (throughout)	Are two choices enough? Can there not be a middle ground such as conditional broad consent? **Recommendation**: Consent options beyond Project Specific Consent or Broad Consent should be permissible such as usage of *Conditional* Broad Consent, or use case consent e.g., allowing specific uses/users to use the data, or allowing entire programs of exploration and research, if appropriate governance is established.

[1] Hayward A., Wodtke L., Craft Aimé., Robin T., Smylie J., McConkey, S., Nychuk A., Healy C., Star L. & Cidro J., Addressing the need for indigenous and decolonized quantitative research methods in Canada, *SSM - Population Health.* 2021; doi: https://doi.org/10.1016/ j.ssmph.2021.100899.

[2] McLemore MR. Reimagining methodological considerations for research studies using 'big' administrative data sets. *Paediatr Perinat Epidemiol*. 2021; 35:491–492. https://doi.org/10.1111/ppe.12796

3. Shared responsibility to protect participants "See Articles 9.1 and 9.11 on research involving First Nations, Inuit and Métis Peoples **[of]** Canada."	All references to "First Nations, Inuit and Métis Peoples **[of]** Canada" to be edited to "First Nations, Inuit and Métis Peoples **in** Canada." We ask that the Indigenous data sovereignty be specified and given distinct recognition.
3. Shared responsibility to protect participants - "This guidance can be applied to other communities when appropriate (Article 2.11)."	Clarification is needed with respect to "other communities when appropriate"; what is considered a group that needs more consultation? Regard must be given to the changing nature of the standards of the day; understanding and definitions of 'other communities will evolve. Governance of biobanks should state what is required for working with 'other communities.'
5. Informed broad consent	There is a blending throughout the guidance of what information could inform potential participants of the use of their personal and personal health information vs. the details of a repository's governance. Participants must be able to educate themselves. If not provided for in the consent form, information on where to access details of a repository's governance including governance mechanisms, sharing of data, and uses of data must be included in the form. Important information must be communicated such as incidental findings and the governance model behind it. Governance information must be made readily available and accessible over time giving consideration for participant population, the changing nature of technology, connectivity challenges, and web formats. **Recommendation**: A template including why content areas are necessary and lay language examples would serve as an invaluable tool. HDRN Canada is available to lead in the development of a guidance template.
5.3 Risks and potential benefits of storage and participation in unspecified research	Inclusion of potential areas of uncertainty should be required such as potential for commercialization future uses.
5.4 Information about the repository and its governance	Many projects indicate they will keep data for XX years. For example, in many cases for RCTs this period is 25 years. Consideration should be given to the long-term storage and the potential for operational changes of repositories over time, including the need for a transfer of custodianship.

	Planning for succession of both researchers and repositories is needed. While we continue to identify and marvel at the potential for data usage, we must equally strive to identify the means of ensuring the protection of these data and to implement safeguards that will protect individuals. Repositories and researchers should be aware of what steps are required to safeguard data. **Recommendation:** Globally data stewards are working together to identify mechanisms such as "data trusts" that can provide "timely, fair, safe, and equitable" access to data. This includes identifying the minimum specifications (i.e., min specs) that will ensure these principles are upheld. We draw attention to the work of Paprica et al., 2020, and ongoing work at HDRN Canada and the CIO Strategy Council Advances National Standards for Responsible Data Sharing.
6. Ongoing broad consent	There is limited knowledge of the ongoing nature of REBs and REB review may not be required in all regions/jurisdictions or for all entities; potential participants must be informed that data may be made available to researchers not subject to the TCPS. A clear directive that this uncertainty exists must be made stated- i.e., cannot say they will be ongoing review if this is not known.

Further Consideration:

Broad consent vs. donation: The use of broad consent in this discussion piece is extensive. At what point does consent become a donation of samples to studies in lieu of consent? If there is a wide range of unspecified future use and no subsequent REB reviews completed, is it not a donation?

Requirement to share data sets in scholarly publications: Increasingly journals are requiring that data sets be made available. Once shared a data set is no longer in the custody and control of the researcher. How does this requirement relate to data repositories and publication of data sets? While the need for transparency is understood, there is concern for the protection of participants. Data research centres that are legislatively unable to disclose personal and personal health data sets are adopting standard phrasing that can be adopted by data repositories.

Need for options: Broad consent is not a panacea, and it would be scientifically unwise to use in all studies. We would not want broad consent for everything as it excludes many people, and we need inclusion for a robust population. Broad consent for unspecified future research, may in particular scare people away. Perhaps consideration for different levels, e.g., broad consent with

some guardrails (private sector research, future research in same field, etc.). REB waivers will still be needed as broad consent could potentially reduce/bias the potential participants.

Further consultation would be beneficial: We recommend the circulation of these recommendations around broad consent to the Canadian privacy commissioners for comment to foster consistency between the REBs and the privacy world when it comes to secondary use of data.

Contradiction: This new endorsement of broad consent is in conflict with the TCPS interpretation on requiring prospective participants to consent to making their de-identified data available for future, unspecified research. The new interpretation indicates it is not ethically acceptable to require prospective participants to consent to making their de-identified data available for future, unspecified research, as a condition of participation. This is a current practice however, for example in clinical trials or as required for journal publications. Does this requirement truly meet the definition of coercion in this context?

Thank you for the opportunity to comment and share our recommendations,

HDRN Canada