Archived: Friday, October 29, 2021 4:02:54 PM
From: Alison Paprica
Sent: Sun, 3 Oct 2021 21:12:49
To: secretariat (SRCR/SCRR)
Cc: Donna.CurtisMaillet@unb.ca; Kim McGrail
Subject: Comments in association with TCSP 2 consultation
Sensitivity: Normal

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1. Province or territory - Ontario
2. Affiliation: University of Toronto, Health Data Research Network Canada, ICES
3. Capacity in which you are submitting the comments: researcher
4. Your main discipline: Health Sciences

I will begin by thanking the Secretariat for preparing documents related to the interpretation and implementation of TCPS 2 (2018) and for providing the research community with the opportunity to respond to those documents. This email includes three personal comments that complement the submission from Health Data Research Network Canada (HDRN) which I have contributed to and endorse in its entirety.

I. Broad consent in research

The website *Proposed Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials* defines broad consent as consent for unspecified research.

Qualitative research studies from around the world, including studies conducted in Canada, have found that members of the public generally express conditional support for research uses of health data.[i],[ii],[iii],[iv],[v],[vi] Extrapolating from these studies, only a small minority of people would be likely to provide broad consent for any and all unspecified uses of their data; but many would like to be given the option of providing conditional broad consent, e.g., consent for non-commercial uses of their data, consent for data to be linked to administrative databases and used in de-identified form in future research studies.

Based on that evidence, and the opportunity to align uses of data repositories with what is known about public preferences, I recommend that the *Proposed Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials* be expanded to include guidance regarding when and how informed broad conditional consent might be obtained.

II. Broad consent in research: 5.4 Information about the repository and its governance

Since 2019, our HDRN-based team has been working to establish practical guidance for data repositories. In Phase I, a team of 19 Canadians, mostly but not exclusively focused on health data repositories, co-developed a peer-reviewed publication describing 12 essential, minimum specification requirements (min specs) for "data trusts" across five categories: legal (1 min spec), governance (4 min specs), management (3 min specs), data users (2 min specs), public and stakeholder engagement (2 min specs).[vii] For Phase II of the project, we have brought together an international team of over 70 people, including representatives from 20 data-focused organizations that have tried applying the min specs to their own data-related practices. The Phase II analyses of these organizations' experience applying the min specs has already identified some important additions and refinements, e.g., a new requirement related to Indigenous data sovereignty. In parallel, the CIO Strategy Council is using the min specs as the foundation for a new standard on data stewardship which was posted for public comment on September 29, 2021.[viii] Phase II of the project is on track to be completed by early 2022, and preliminary results can be shared before that date.

The list of 12 bullet points under *Proposed Guidance Regarding Broad Consent for the Storage and Use of Data and Human Biological Materials 5.4 Information about the repository and its governance* includes some, but not all, of the min specs. We would welcome the opportunity to share learnings from our min specs project to inform TCPS 2 Guidance related to information about repositories.

III. The review of multi-jurisdictional research: 3.3 Who is responsible for ethics review of minimal risk research involving multiple institutions?

As noted in *Ethics Review of Multijurisdictional Research – Proposed Revised Guidance*, there may be cases where it is appropriate or preferable for a research ethics board (REB) that is not the Principal Investigator's to serve as the REB of record, for example, if there is an REB with greater expertise in the research topic.

In the case of database-based research, i.e., research that uses data repositories without direct contact with individual human participants, many researchers and REB members may not have the knowledge or skills to assess or address risks related to data protection, privacy, bias in datasets and other data repository-related topics. Accordingly, I strongly endorse the HDRN recommendation to establish a purpose-built board of record for database-based research with HDRN playing a leadership role in the establishment of the new purpose-built REB.

Thank you again for the opportunity to comment on the draft guidance, and for your consideration of my suggestions.
Sincerely,
-Alison

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[i] Cumyn, Annabelle, Adrien Barton, Roxanne Dault, Anne\u8208?Marie Cloutier, Rosalie Jalbert, and Jean\u8208?François Ethier. "Informed consent within a learning health system: A scoping review." Learning health systems 4, no. 2 (2020): e10206. https://doi.org/10.1002/lrh2.10206

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[viii] CIO Strategy Council. (2021, September 29). Public Review. CAN/CIOSC 100-7:20XX (D2), Data governance – Part 7: Operating model for responsible data stewardship https://ciostrategycouncil.com/standards/public-review/