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From: REB
Sent: Mon, 4 Oct 2021 13:36:06
To: secretariat (SRCR/SCRR)
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal
Attachments:
TCPS 2 Proposed Revisions Laurier Response.pdf

Good afternoon,

On behalf of Wilfrid Laurier University's Research Ethics Board, I have attached our comments and questions regarding the proposed guidance.

Please find our demographic information below:

Province or territory: Ontario

Affiliation: University

Capacity in which we are submitting the comments: Institutional Research Ethics Board

Main discipline(s): Behavioural Sciences, Health Sciences, Humanities, Interdisciplinary, Natural Sciences, and Social Sciences.

Thank you for giving us the opportunity to provide feedback on this new guidance.

Samantha

Samantha Moeller, MA

Research Ethics Coordinator

Office of Research Services

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TO: Secretariat on Responsible Conduct of Research
DATE: October 4, 2021
RE: TCPS 2 (2018) - Proposed Revisions for Public Consultation

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Dear Panel on Research Ethics and the Secretariat on Responsible Conduct of Research,

In response to the call for public comments, Wilfrid Laurier University's Research Ethics Board (REB) is pleased to provide feedback on the proposed guidance related to the interpretation and implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018)*. Laurier's REB welcomes the proposed guidance and has identified areas where further clarification is needed. Please find attached comments submitted on behalf of Laurier's REB for your consideration.

Thank you for providing us an opportunity to be involved in this process.

Sincerely,

Jayne Kalmar, PhD
Chair, University Research Ethics Board
Wilfrid Laurier University

Sybil Geldart, PhD
Vice-Chair, University Research Ethics Board
Wilfrid Laurier University

COMMENTS ON PROPOSED GUIDANCE

Please note, the line numbers used throughout refer to the line numbers presented in the linked documents.

Ethics Review of Multi-Jurisdictional Research – Proposed Revised Guidance

Laurier's REB would like to offer support for this additional guidance. We agree that a single REB review would not compromise participant protection and would lead to a more seamless process of ethics review. At Laurier, there is already an expedited review process in place for multi-jurisdictional research which has been approved by another institution. In this process, we accept a copy of the application approved by another institution and focus our review primarily on local considerations. While the proposed guidance will require some additional consideration prior to final implementation, we believe it will streamline the review process for all involved. However, we do have several questions and recommendations regarding the proposed revised guidance that we believe should be considered and addressed ahead of implementation. Additionally, we also recommend that this guidance undergo further consultations once additional revisions are made after this initial consultative process. Our initial suggestions for consideration are found below.

- **Lines 30 – 35**: The policy acknowledges that a factor likely contributing to the current approach to multi-jurisdictional review is the broad interpretation of what constitutes research carried out within an institution's auspices. As such, Laurier's REB believes that it is important that Panel on Research Ethics (PRE) and the Secretariat on Responsible Conduct of Research (the Secretariat) provide an updated interpretation of what should be considered to be within an institution's auspices and jurisdiction prior to implementing the aforementioned guidance. We recommend that the PRE and the Secretariat reconsider including the use of bulletin boards and email lists for recruitment as examples of what is considered to be within the jurisdiction/auspices of an institution (as outlined in TCPS 2 Interpretation, Multi-Jurisdictional Research, 1). Requiring local Boards to review research that uses such minimal resources when there is no local researcher

involved in the project will unnecessarily hinder the progress of research and cause significant burdens and delays for both researchers and REBs, even under the proposed multi-jurisdictional model. Instead, we recommend that criteria be developed where these kinds of projects are considered exempt from multi-jurisdictional review with a note that there may be additional institutional requirements in place to obtain permission to utilize institutional resources for recruitment.

- **Line 75 – 80**: Laurier's REB recommends that the PRE and the Secretariat reconsider whether the guidance should be considered mandatory for **all** minimal risk research conducted under the auspices of multiple institutions. While we recognize the importance of institutions adapting this policy and taking a consistent approach to multi-jurisdictional review in order to not unnecessarily hinder the progress of research, there are some concerns with the broad scope of the proposed guidance:
    - Further consideration should be given to address lines 30-35, and more detailed guidance provided on the types of research that would be considered eligible for this review process and cases where projects may be exempt from multi-jurisdictional review. For example, clearly defining "resources" in the context of multi-jurisdictional review is important to ensure consistent application of this guidance.
    - As noted in lines 68-69, "…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." While this process may be sufficient in the vast majority of cases, there should be consideration given to cases where this review process may not be appropriate or sufficient (e.g., local considerations are not taken into account when designing the study). In cases where this process may not be the best-suited review process, the result may be numerous missed local circumstances and/or substantive missed issues, which would defeat the purpose of this review process and unnecessarily increase the workload for both REBs and researchers. Developing clearer criteria on when this review process is mandatory and cases when another process may be better suited is important to ensure consistent application of this guidance.

- **Lines 86 – 90**: We recommend that the language be changed from "should have considered the local circumstances" to "must have considered the local circumstances". If local circumstances have not been incorporated in the proposal and design, then it would not be possible for the local Board to accept the review. The onus should be on the research team to ensure that the application meets specific criteria for multi-jurisdictional review and includes sufficient information.
- **Lines 86 – 90**: We recommend that the guidance make a distinction between major research ethics concerns and missing information (i.e., missing local circumstances). If the research team has not incorporated local circumstances into the application, then this should be considered an incomplete application. At this stage it would be appropriate to have the researcher return to the Board of record with a revised application taking this into account, as they would be in the best position to update the application accordingly and provide missing information to the Board of record after receiving direction from their local Board. Putting this onus on the researcher is appropriate as they should be ensuring that they are providing sufficient information to allow for a multi-jurisdictional review under this new model. Alternatively, if there is a major research ethics issue that was not considered related to the local context, this would be appropriate to be resolved between the local Board and Board of record as suggested.
- **Lines 98 – 107:** The current guidance puts the onus on the principal investigator (PI) to determine the most appropriate REB. It is recommended that this guidance be revised as the PI is in most cases not in the best position to determine which Board should serve as the REB of record when factors such as the expertise and location of research activities need to be considered. For example, the PI may not be familiar with the expertise of the Boards at the various institutions involved and even if they were familiar, they would not be as familiar with the expertise available as the Boards are themselves. Further, requiring a PI to justify to their home REB why another REB would be better suited requires additional work for the PI, making it unlikely that a PI would seek this out even when it would be appropriate.

  Following the proposed guidance, the REB would only be able to determine whether they have appropriate expertise and/or be informed of the location of research activities after the PI has selected the Board of record (default being the

REB at their home institution) and submitted an application. If upon receiving the application, the REB does not have appropriate or sufficient expertise, they may need to seek out an ad hoc review. Similarly, if the research activities are taking place at another site, the REB of record may not be best suited to complete the review and the chances of there being substantive issues or local circumstances identified by the local REB are increased. These potential issues may complicate the review process and increase timelines which could be avoided by ensuring the appropriate REB of record is selected. To avoid this, it would be beneficial if PIs were required to consult with their REB ahead of submitting a multi-jurisdictional application to confirm that their REB should be the REB of record, or whether another eligible collaborating institution may be better suited to serve as the REB of record. The PI's REB would then be responsible for confirming the willingness of another REB to serve as the REB of record if deemed necessary.

- **Lines 129 – 133**: While REBs communicating amongst themselves to resolve some issues is valuable and important, there are many instances that would require the PI to take action to resolve issues. Is it the intention of this section that the REB of record would communicate any further requested changes back to the PI? If so, this should be made clearer. As currently worded, it seems as though the REBs are responsible for addressing remaining issues.
- **Lines 122 – 146:** Lines 160 – 163 indicate that for higher than minimal risk research where there is an opportunity for local review, the research may begin at other sites (if appropriate), but that research may not begin at a local site until review is complete at that local site. There is no similar guidance provided on expectations for commencing minimal risk projects. Is the expectation that research will not commence until all eligible REBs acknowledge the decision of the REB of record and these acknowledgements are received by the REB of record? How and by whom will all involved institutions be informed that all acknowledgements have been received by the REB of record and the research is approved to commence? It is important to note that funds for multi-jurisdictional research projects may be held at multiple institutions involved. For administrative purposes such as the release of funds with compliance requirements, institutions where the funding is held will need to be informed of the research project start date to proceed with releasing the funds. Further guidance on this process and expectations should be included in the section describing the process for researchers and local REBs to follow.

- **Lines 143 – 145:** It would be helpful to expand this section to provide more detailed guidance on continuing research ethics review requirements such as annual reports, reports of unanticipated issues, and requests for changes to approved research, and how these processes should be handled for multi-jurisdictional reviews under the newly proposed guidance. For example, if a request for a change to an approved project is approved by the Board of record, is it the PI's or the Board of record's responsibility to send it to the other REBs, if required at all? Similarly, do annual reports or reports of unanticipated issues need to be submitted all research sites, or just submitted to the Board of record?

Proposed Guidance Regarding Broad Consent in Research for the Storage and Use of Data and Human Biological Materials

Laurier's REB would like to offer support for this additional guidance. However, clarification is requested.

- **General Clarification:** In order to provide more meaningful comments on this guidance it would be helpful to understand how the proposed guidance is intended to fit into the current TCPS2 document. Will this be incorporated into Chapter 3: The Consent Process or Chapter 5: Privacy and Confidentiality? Will this require the addition of new articles or revisions to existing articles? For example, will the Application of Article 5.5A be updated to consider when obtaining broad consent at the beginning of a study would be considered satisfactory versus requirements for ongoing broad consent?
- **Lines 64-68**: While the proposed guidance notes that researchers may need to seek further consultation or permissions about broad consent when data or human biological materials are from a specific or unique community or a group, further clarification would be welcomed about which party should ultimately be providing permission for broad consent. For example, would it be the participant or a government in a particular community, or a combination?
- **Line 196 – 210**: The requirement for ongoing broad consent has been identified, however it is noted that in some cases, ongoing consent may be impracticable and limited to a one-time event that takes place when the data or human biological materials are collected. The proposed guidance notes that deviations or limitations to the notion of ongoing consent must be justified to an REB and explained to participants. Further clarification on this is requested. For example,

are there specific criteria that must be met in order to justify deviations or limitations to the notion of ongoing consent?

- **Lines 234 – 239**: For the purposes of this guidance a repository is defined as "*a data repository or biobank*" and a data repository is defined as "*a collection of research data*". The definition provided is vague and seems to apply to any researcher planning to store data for use in potential future research studies. The proposed guidance appears to rely heavily on this term, so it would be useful to provide a more detailed definition of the term and further clarification on what is required to establish a repository and expectations for the governance of a repository. For example, line 125 notes that for broad consent to be informed, it must include information about the repository and its governance (if known). It is unclear when information about a repository and its governance should be known versus when this may not be known and would not be necessary. In what cases would details of a repository's governance be relevant to include in the consent versus considered distracting (lines 106-115)?

Cell Line Exemptions

Laurier's REB does not regularly review research in this area, however we would like to offer our general support for this proposed guidance and have a question for clarification:

- **Lines 24 – 27 and 43**: In the background provided on this guidance it is noted that the terms of consent are rarely known in the case of de-identified or anonymized cell lines. In the proposed guidance on broad consent lines 56 – 58 note that "*Researchers who intend to make their collections of data or human biological materials available to other researchers not subject to the TCPS must consider the repercussions of this decision for participants*." Following this guidance, are there additional considerations for researchers accessing data or human biological materials available from sources not subject to the TCPS?

Research Involving Totipotent Stem Cells – Proposed revisions to the TCPS 2 (2018) Chapter 12, Section F

Laurier's REB agrees with the proposed changes and has no further comments.