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From: Julie Joza
Sent: Fri, 1 Oct 2021 17:29:34
To: secretariat (SRCR/SCRR)
Cc: Kelly Grindrod; Hilary Bergsieker; Bruce Muirhead
Subject: TCPS 2 CONSULTATION
Sensitivity: Normal
Attachments:
UWaterloo REB feedback_TCPS2 proposed changes_2021-10-01.pdf

Dear Panel on Research Ethics,

Please find attached feedback from the University of Waterloo REBs on the proposed changes to the TCPS2. The requested demographic information is below.

1. Province: Ontario
2. Affiliation: University
3. Capacity: REB members
4. Main Discipline: Interdisciplinary (includes Behavioural Sciences, Engineering, Health Sciences, Humanities, Social Sciences)

Best regards,

Julie

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Julie Joza, MPH (she/her)

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The Office of Research acknowledges that we are living and working on the traditional territory of ý the Attawandaron (also known as Neutral), Anishinaabe, and Haudenosaunee peoples. The University of Waterloo is situated on the Haldimand Tract, the land promised to the Six Nations that includes ten kilometres on each side of the Grand River.

October 1, 2021

Secretariat on Responsible Conduct of Research
Canadian Institutes of Health Research
160 Elgin Street, 9th Floor
Ottawa, Ontario K1A 0W9
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Dear Panel on Research Ethics,

On behalf of the Research Ethics Boards at the University of Waterloo, please find attached a summary of our member's collective feedback on the proposed changes to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 (2018)).

As outlined in our summary, we appreciate all the work that went into the development of this first draft of the four documents related to the interpretation and implementation of the TCPS2 on the following themes:

- the review of multi-jurisdictional research;
- broad consent in research;
- the review of research involving cell lines; and
- research involving totipotent stem cells.

Further guidance on ways to support researchers and REBs in these areas, and specifically the review and conduct of multi-jurisdictional research, is something we have been looking forward to for some time.

If questions arise concerning our feedback, please feel free to contact me directly.

Sincerely,

Julie Joza

Julie Joza
Director, Research Ethics

c.c. Hilary Bergsieker, Chair, Human Research Ethics Board
Kelly Grindrod, Chair, Clinical Research Ethics Board

October 1, 2021

University of Waterloo Research Ethics Board Feedback to the Panel on Research Ethics

A. Multi-jurisdictional Research

We appreciate all the work that went into the development of this first draft to support multi-jurisdictional research and support the move to a REB of record review model. Further guidance on ways to support multi-jurisdictional REB review is something we have been looking forward to for some time. The recommendations to identify a REB of record for minimal risk research (and potentially more than minimal risk research) is a move that we support to break down the barriers to multi-site research. We do have several comments that we wish to share with the Panel as we would like to see greater clarity on how to implement this new guidance. We are concerned that without added clarity, researchers and REBs may continue to endorse the current status quo. We offer the following comments and recommendations to add clarity and provide researchers and REBs with the confidence to adopt the proposed change to a REB of record review model.

Line number	Feedback
74 and 100 – reference to "eligible institutions"	Although defined in the footnote on page 1, greater clarity could be achieved by referring to "eligible institutions receiving Tri-Agency funds" in the main body of the document, as the information in the footnote may be lost or missed by the reader.
78-80 – bullet points identifying the type of minimal risk research that is mandatory for a single REB review	More clarity is needed with specific examples referencing participant recruitment at more than one eligible institution. The current examples are focused on researcher affiliation and resources. It would be helpful to provide relevant examples of "involvement" and "resources" to identify levels of collaboration covered by this guidance. For instance: "Noting that these examples are not exhaustive, researcher 'involvement' might include study design, collecting or analyzing data, and co-authoring papers, and 'resources' could include provision of funding, personnel, or access to participant populations." If this recommendation is adopted, revising the first bullet point to say "research involving researchers" rather than "research conducted by researchers" would improve consistency. This guidance also provides the opportunity to clarify the scope of multi-jurisdictional research and provide specific examples of what types of collaboration require multi-jurisdictional review at one or more institutions. A table or decision tree would be a helpful tool to outline specific examples of researcher collaboration and if local REB review is required. These tools would help researchers and REBs

	determine if this guidance applies or not. The examples currently used in the guidance are a bit too vague. Specific examples would provide greater clarity. For example, if a researcher is only receiving results and helping to write a paper is the local REB required to acknowledge the study? Does this change if the researcher is receiving and analyzing the data? Is there a consideration if institutional funding is supporting the research?
83 – reference to REB of record review	Here it states the decision of the REB of record "and reasons, along with final study materials, would then be available to the REBs of all sites, for acknowledgement." Revising "would" to "will" is recommended to ensure the REB of record is required to share information available if requested.
82 – 86 – requirements for REB of record	This section reads as if the review by the REB of record will be done by the full REB, whereas the local review/acknowledgement would be conducted by a single REB member. Clarity is needed to know if the review by the REB of record for a minimal risk study can also be conducted by a single REB member if that is the procedure of the REB of record, for instance by stating "a single REB of record will conduct the ethics review (including the option to use delegated review if that is the procedure of the REB of record)."
84 – reference to consideration and acknowledgement	Because multiple local REBs may be involved, it would be clearer to state: "Ideally, at each local REB, that consideration and acknowledgment would be done by a single individual."
90-91 – reference to local REB identifying a missed issue and flagging this for the REB of record	A definition of what constitutes a "substantive" issue would also be helpful (e.g., is this a major concern that would otherwise have led the local REB to withhold clearance?)
97 - responsibility for ethics review of minimal risk research involving multiple institutions	For greater clarity, suggest revising this heading, "Who is responsible….," to "Identifying the REB of Record." This section should then outline in separate paragraphs, how to identify the REB of record and the responsibilities of the REB of record. A decision tree or similar tool would be useful to outline the broad concepts that are applicable, but specific enough to guide the elements of responsibility.
100 – reference to identifying the REB of record	Additional clarity would be helpful in this section to outline how the REB of record should be chosen when the PI has multiple affiliations across several institutions. If the PI is the person named as the lead on the grant or contract, please consider revising to reference "the REB of the (lead) principal investigator (PI) named on the grant or contract" and specifying how the lead PI is defined when the study is not funded. For unfunded research, in most cases, the institution has no record of the

	research study other than a research ethics application or another type of ancillary review.
105-107 – justification to home REB and demonstration of other REB willingness	A concern that arises is there could be REB "shopping" taking place to identify a REB who will review the study faster rather than the focus being on expertise, given that PIs often will not be aware of the expertise of REBs from other institutions. A decision-making tool, as proposed earlier, would help avoid inappropriate selection of the primary REB. Further, it would be important to provide guidance on how the PI will be expected to "demonstrate" the other REB is willing to serve as the REB of record (e.g., providing an email from the REB chair).
109-120 – local REB to advise REB record	Greater clarity about the typical extent of consideration or review expected from the local REB(s) would be helpful. These guidelines indicate that "normally" the local REB acknowledges the clearance decision, but do not explain how to identify the cases that "exceptionally" call for a local REB to also review the study and identify issues that may impact the ethical conduct of the study. Could such review be initiated at the request of the REB of record, or by the individual receiving the protocol on behalf of the local REB, or by either party? Further clarity is needed as to the role of the local REB (e.g., specifying "without further review required" at the end of the initial sentence about acknowledging the review).
122-145- process for researchers and local REBs to follow	A clear and detailed chronological process outlining how REBs are expected to work collaboratively would be most helpful to ensure there are no barriers to implementing the REB of record review process. This outline should include an explanation of when the REB of record should provide approval and when the researchers could start the study (i.e., can they start the study after the REB issues clearance or to they need to wait until all acknowledgements are received). It would also be helpful to distinguish between the role and responsibilities of the REB of record and the local REBs. Are the steps for minimal risk research meant to be something like the following? 1. The REB of record is confirmed (by default at the institution of the project PI, unless the PI demonstrates that another REB is better suited because of their expertise). 2. The REB of record receives an ethics application and works with the lead researcher (i.e., PI) to address the ethical issues. 3. Researchers at other institutions provide their own local REBs the ethics clearance from the REB of record and the full study documentation.

	4. An individual at each local REB reviews the materials to identify local or substantive issues and work with the REB of record to resolve these issues (if any) before the local REB sends an acknowledgement to the REB of record and the local researcher(s), recognizing its clearance. Creation of a master REB of record application could support communication among REBs as well as outline the processes for communication and how acknowledgements will be shared with the local REBs. It would be helpful if this section also provided guidance about processes that are to be followed post-approval. For example, what processes are researchers at the local site to follow if there needs to be an amendment to the study protocol, report an unanticipated problem, renew the study for another year (continuing review)? Are all such responsibilities handled by the REB of record?
123-125 – expectation for researchers to provide study documentation to local REB	Please clarify in this guidance when researchers can begin their study. If the study cannot begin until all local REBs have provided acknowledgement to the REB of record, the researchers will be highly motivated to provide these materials. However, if the study may begin following clearance from the REB of record (i.e., without local acknowledgement) researchers are often preoccupied and working quickly to begin a study and may not provide the study documentation to the local REB in a timely fashion. Consider putting the onus on the REB of record to provide the information to the local REB (or on both the researcher and the REB of record and ensure appropriate coordination). Although an additional responsibility for the REB of record, it will ensure the local REBs are provided the required documentation that is needed.
125-128 – definition of terms 'consider these documents' and 'acknowledge the ethics approval' is needed	It is unclear from this section how the local REB is to "consider" the approved study documentation for local circumstances and issues requiring further review by the REB of record if the REB of record has already given ethics approval of the study. If the study has been approved by the REB of record, and then a local REB identifies substantive local concerns, is a process needed for the REB of record to suspend clearance or otherwise pause the research? This section is titled "Process for researcher and local REBs to follow" but the section does not appear to be written in a stepwise fashion. This section should be revised as such.

129-133 – local or substantive issues raised by local REB	This paragraph outlines an important detail. As noted above, it is unclear how the local REB is to "flag" local or substantive issues for the REB of record (e.g., studies with local Indigenous communities or agencies who may have their own research or ethics approval process or inter-institutional agreements).
134-138 – timelines for review	This section should indicate this is a requirement for researchers. As noted, researchers are often preoccupied and working quickly to begin a study and may not provide the study documentation to the local REB in a timely fashion. It is unclear if the REB of record will hold the local researchers accountable to the timeline otherwise the ethics approval of the study will be withheld until completed. Further, it is unclear if the decision of the REB of record to approve the study is shared prior to the local REB review to identify local or substantive issues. It makes the process clearer if this were the case. As noted, the process for collaborations and communication from the REB of record to the local REBs needs to be expanded and more clarity provided.
139-145 – researcher responsibility to send decisions and approved materials to their local REB as well as amendments or other changes	As noted, researchers are often preoccupied and working quickly to begin a study and may not provide the study documentation to the local REB in a timely fashion. Consider putting the onus on the REB of record to provide the information to the local REBs. Although more work for the REB of record, it will ensure the local REBs are provided the required documentation.
147-148 – how does this guidance apply to ethics review	The title, "How does this guidance....," would be better worded as "How can this guidance be applied…" to indicate that this guidance is optional for studies that are greater than minimal risk.
149-163—more than minimal risk	The heading for this section indicates that this section pertains to greater than minimal risk research only and describes how local REBs may have an opportunity for local review. There does not seem to be a different process for minimal risk research other than the timeline of 3 weeks compared to 6 weeks for greater than minimal risk research. Line 160 states "in situations where all local REBs have not completed their review...." which suggests the research may begin, and at the sites where the local REB has completed the review, but not at the sites where the local REB has not completed their review. It is unclear if this is only possible for research that is greater than minimal risk or if this same process can be applied to studies that are minimal risk. It might be helpful to note that regardless of the risk level, research

	can only begin at the sites where the researchers have obtained the necessary approvals to proceed. As REBs may judge the risk level associated with a project differently, more information and guidance for REBs on how to address conflicting opinions on risk level is needed particularly when conducting research with vulnerable populations. Emphasizing clear communication between the REB of record and the local REBs may be a way to address these differences. This guidance would also create mutual understanding around issues such as the secure transmission of information or data. A master application held by the REB of record could be created for use by REBs who act as the REB of record and include a checklist or section for tracking multi-site/local REB approvals.
160 – 163 – REB of record approves study prior to local review	Please provide more clarity about what research activities are permitted if the REB of record grants clearance to the protocol before one or more local REBs have completed their review for local issues (e.g., could researchers from institutions without a completed local review still be named on the consent form or contribute resources to be used at other sites where research is commencing?). Additionally, it would be important to highlight whether there are any activities that should not be permitted until all local REBs have completed their review for local issues.
General comment: Use of should vs. shall	Throughout the document the term "should" was used. The term "shall" may need to be used to identify the details that a REB and researcher must do if they choose to follow the guidance provided for multi-jurisdictional review.

B. Broad consent for the storage and use of data and human biological materials

Line Number	**Feedback**
59-63 – assurances for REB review of subsequent research	Clarity is needed to understand situations when a researcher would not be able to make an assurance to participants that any subsequent or future research using the data or biological materials could not undergo a REB review.
76 – 78 - limitations to withdrawal	Examples should be provided of an acceptable reason to anonymize data or biological specimens. Further guidance on this for researchers and REBs is needed.
151-152 – respecting the terms of consent	Further explanation is needed to expand this point and outline how the terms of consent will be respected in research. The examples provided need additional context to provide more fulsome guidance for researchers and REBs.

185-187 – informing participants	Consideration should be given to adding a point outlining what researchers are to do if the participant is now deceased and unable to provide consent for use by a third party. Is the information not used or are they to contact a family member for consent? Further, if the data collected has been de-identified and no longer attributable to the participant, researchers will be unable to ensure the participants are informed of a third-party use. Often, requests for uses by a third party do not arise until after the data or biological materials have been stripped of any identifiers. Should guidance be for researchers to outline that in some situations they should not de-identify data or biological materials (e.g., in situations where a secondary or incidental finding may be possible or where a third-party request to use the data may arise)?
196-198 – ongoing broad consent	The recommendations to recontact participants concerning ongoing consent is not an activity most researchers will be familiar with and therefore should be emphasized.
General comment: Use of should vs. shall	Throughout the document the term “should” was used. The term “shall” may need to be used to identify the items that are required by researcher or REBs.

C. Cell line exemptions

Line Number	Feedback
55-65 - terms of the exemption are no longer filled	Clarification is needed for researchers that outline the steps they need to take. For example, should the researcher pause the study after the issue has been identified and wait until the REB approval has been obtained to restart?
103-104 – research involving the donor or other participants in conjunction with cell line requires REB review	This statement is a crucial point and is lost in this latter section of the document. This point should be moved to the main section to emphasize its importance to researchers and REBs.
149 – impossible or impracticable to seek consent	Because it is understood that consent would have already been obtained, if possible, from the donor to have the identified cell line in a biobank in the public domain, examples of circumstances where it may be necessary for researchers to obtain additional consent are needed. If this step is necessary, further clarification would be helpful for both researchers and REBs.
151, 162- 165 – research is unlikely to harm the participant	Clarification is needed regarding harm beyond the participant such that should the consideration of harm expand beyond the participant to their family.
155 – available from public catalogues	Helpful guidance to include here would be to add a few real-life examples of public catalogues.
162-165 – considerations of harm	The tolerance level of harm for REBs and for participants and their families may be quite different than that of the researcher. A statement outlining this distinction would be helpful, emphasizing that a participant-centred approach must be taken when considering the use of identified cell lines for research.

D. Research involving totipotent stem cells

Line Number	Feedback
90 – research not conforming to this policy	A description of the implications if the research does not conform to the policy should be described.
137 - consent requirements	In addition to referring to article 3.2, should there be a reference to the new proposed guidance on broad consent.