## BROCK UNIVERSITY RESEARCH ETHICS BOARD Tuesday, April 13, 2021 12:00 – 2:00 p.m. Teams

## Minutes of the HREB Meeting

**Attendance** 

Shawn Beaudette Stephen Cheung Nicole Chimera Gail Frost Kimberley Gammage Carly MaGee (non-voting) Megan Magier Jennifer Matunin-Brown Maureen Shantz Craig Tokuno Terrance Wade Danielle Williams Jenalyn Yumol Regrets

Lori Walker (non-voting)

| M  | MINUTES                  |   |  |  |  |  |
|----|--------------------------|---|--|--|--|--|
| IT | EM                       | DISCUSSION  | ACTION   |  |  |  |
| 1  | Motion to approve Agenda |   | Motion to approve: TW Seconded: MM All in favour  Motion to approve: SB Seconded: JY All in favour |  |  |  |
| 2  | Discussion               | <ul> <li>Guideline for Multi-Jurisdictional Research</li> <li>The goal of reviewing this document was explained to the board: to establish updated Brock guidelines that match the new TCSP2 interpretations on multijurisdictional research.</li> <li>There is some flexibility in how we interpret and apply the content of the TCPS2, and some of the interpretations that the Panel on Research Ethics (PRE) recently published conflict with how we were planning to update our Brock guideline. As such, we are revaluating our previous discussions and bringing these questions to the board for further input.</li> <li>The purpose of today's meeting is to get insight into board's interpretation of the TCPS2; input on how we should review and process multi-jurisdictional applications (various formats); how we should communicate these guidelines to researchers so they are aware of their responsibility in multi-jurisdictional projects.</li> <li>The Chair reviewed relevant TCPS2 definitions pertaining to multi-jurisdictional research:         <ul> <li>"Research involving humans that may require the involvement of multiple institutions and/or multiple REBs (Chapter 8, TCPS2)."</li> <li>"Institutions are accountable for research conducted under their auspices, irrespective of the location where it takes place."</li> </ul> </li> </ul> |  |  |  |  |

- "Research involving humans that may require the involvement of multiple institutions and/or multiple REBs includes, but is not limited to, the following situations:
- (a) a research project conducted by a team of researchers affiliated with different institutions;
- (b) several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
- (c) a research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;
- (d) a research project conducted by a researcher who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital. See Application of Article 6.1);
- (e) a research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or X-ray technicians, social workers and school teachers); or
- (f) a research project that researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country." (TCPS2).
- Our current Brock guideline interprets this Chapter of the TCPS2 in the following way: "any research that will be conducted by or associated with a member of the Brock University community... that will in any way make reference to their affiliation with Brock University or use the resources (financial, physical, or human) of Brock University, will require clearance from the Brock University REB, regardless of the members' contribution or the location of the research site."
- A recent interpretation published by PRE was reviewed: Where an individual working under the auspices of an institution is involved in research solely as a service provider to researchers in other institutions, should the REB of that institution review the research? PRE's answer to this is as follows: The individual in question would not be required to submit the research for research ethics board (REB) review within his/her institution so long as the individual is not a member of the research team, he/she does not benefit from authorship on publications, and his/her contribution is limited in nature to a service that does not in and of itself constitute research involving humans as defined in TCPS 2 (see application of Article 2.1). If the service provider meets the above criteria, or falls within an exception set out in his/her institution's policy, it would be sufficient for the individual to get confirmation from the principal investigator (PI) that this research has been reviewed by the PI's institutional REB so long as it is compliant with TCPS 2.
- Board members discussed whether this happens in practice – do Brock researchers submit these types of

- files/projects to the REB for review (e.g., regardless of where the research is taking place, regardless of their involvement). If not, should it continue to be part of our guideline? Based on PRE's interpretation, it seems to suggest that REB review is required in these instances unless there are exceptions that are set out by each institution.
- With these guidelines in mind, we need to think about the criteria we want to put forth, so researchers know when they need to submit a REB file for review (in a multi-jurisdictional context) and when there are exceptions. In terms of exceptions, they must be within reason and keeping with the spirit of the TCPS2. Because of the ability to develop institution specific exceptions, there appears to be a large variance in how these projects are being handled from a REB perspective across Canada, despite everyone following the same policy (TCPS2).
  - For example, University of Alberta and British Columbia require local review by their REB if their researchers will benefit from authorship or are listed as part of the study team (regardless of authorship), respectively.
  - Whereas, local review is not required (regardless of authorship) at University of Western and Toronto if their researchers are only involved in a peripheral role or providing intellectual support, respectively.
  - Our current Brock guideline most closely aligns with the Alberta and UBC guidelines (e.g., as long as the researchers from those institutions are part of the research team or listed as a coauthor on the publication, they are asked to obtain local review from their REB).
- Board members discussed our underlying mandate as the REB: to protect research participants. If a researcher is reading a manuscript and providing feedback or working with de-identified data, is there any additional risk to participants for someone taking on that role?
- Different multi-jurisdictional scenarios were reviewed for board discussion:
- "An external PI e-mails a Brock researcher to ask for help with participant recruitment. The Brock researcher is asked to post a recruitment poster to students in their class; interested students would then contact the external PI for further details about the study. No data collection would occur at Brock University. The project has received ethics clearance from the external PI's REB."
  - The majority of the board felt that this would not constitute multi-jurisdictional research and should not require Brock REB review.
  - A posted interpretation from PRE on this topic was reviewed for board members: The issue to consider is whether the research is being conducted under the jurisdiction or auspices of

- the other institutions as well, which would necessitate REB review at the other institutions. The determining factors include (1) the extent and nature of the other institutions' involvement, and (2) whether it is necessary for the researcher to collaborate with the other institutions in order to carry out the research. If the researcher is seeking the collaboration of
- If the researcher is seeking the collaboration of staff of other institutions and/or using the resources of those institutions (e.g., bulletin boards, email lists, meeting rooms, equipment) to recruit members of the institution or for the purposes of data collection then the research would be under the auspices of these other institutions. The research would require ethics review by REBs of the other institutions in addition to the researcher's REB (see <a href="Article 8.3">Article 8.3</a>). The level of REB review may be adjusted in accordance with a proportionate approach to research ethics review (see <a href="Article 6.12">Article 6.12</a>).
- However, if recruitment and/or data collection involving an institution's members as prospective participants is done through other means that do not involve the resources of the institution, the research would not fall under its auspices and would not be subject to review by its REB. For example, if names and emails of faculty or department heads are publicly available on websites or through some disciplinary association and the researcher uses this information to recruit them as participants, then REB review at the researcher's institution would suffice. Similarly, if the researcher approaches members of the institution in a public space outside the institution for recruitment and/or data collection (e.g., on-thestreet survey), the researcher would only need approval from his/her home REB.
- Board members still agreed that in this context, the Brock researcher is acting as a service provider and would not benefit from authorship, so in that sense, it should not require REB review. The office explained that this would still be considered a multi-jurisdictional project though because it is using resources from two different institutions. As such, the external PI themselves would have to receive clearance from the Brock REB before the Brock researcher would be able to pass on the study information. This would not be the responsibility of the Brock affiliate (to secure Brock ethics), but that of the external researcher.
- The office explained that Brock actually has as policy in the Faculty Handbook (3C 2.2.1[b: i-ii]): All human participant research must undergo ethics review prior to commencing and receive

clearance from a Brock University Research Ethics Board regardless of whether the procedures used are invasive or non-invasive. This policy applies to funded and non-funded research involving human participants conducted in any location on or off campus by Brock University faculty, staff, graduate students, undergraduate students and to anyone conducting research under the auspices or within the jurisdiction of Brock University, that is, where the research involves the use of the institution's resources (e.g., physical space not typically open to the public, staff time, access to information not generally available to the public), and/or the research involves collaboration with anyone affiliated with the institution. This does not include participants who may be affiliated with the institution but are recruited without the involvement of the institution (e.g., through a news media advertisement or through an email to a publicly accessible email address).

- The Chair explained that Western University's guideline explains that local review is not required for recruitment without consent (meaning the Western PI distributes recruitment materials for an external researcher but otherwise is not involved in the project). This is compared to SFU who mirrors our Brock statement.
- The board admitted difficulty understanding why acting as a "bulletin board" would require them to obtain REB review.
- The second scenario was presented for board discussion: A Brock researcher informally brainstorms potential project ideas with an external PI. Due to their intellectual contribution to the conceptualization and design of the study, the Brock researcher is asked whether they wish to be recognized as a co-author on the manuscript. The project has received ethics clearance from the external PI's REB.
  - Researchers cannot retroactively apply for REB clearance, so how would we expect them to handle this? The researcher would not be interacting with participants or data and as such has a very peripheral role on the project (i.e., acting for intellectual support).
  - A board member asked a question for clarification: If a researcher was listed as an investigator on the REB application, does this automatically mean the project is multijurisdictional?
  - The board felt that we need to come back to the protection of participants when writing these guidelines.

- The consensus after the discussion was that this scenario should not require REB review, but the board was undecided as to whether it was multi-jurisdictional.
- The third scenario was presented for board discussion:
   A Brock researcher visits a collaborator's lab at another institution to carry out a new research project. The Brock researcher is involved in data collection (while at the collaborator's lab), data analysis and manuscript writing. The project has received ethics clearance from the collaborator's REB.
  - The majority of the board agreed this was a multi-jurisdictional project and should require Brock REB review.
  - The board asked: if the researcher in this scenario did not have access to the data, would that change our assessment? Should our requirements depend on the identifiability of data and participants?
- The fourth scenario was presented for board discussion: An external PI e-mails a Brock researcher for help with the analysis of recently collected data. The Brock researcher would be sent a set of de-identified data so that they can perform statistical analyses and contribute to the writing of the manuscript. The Brock researcher would be recognized as a co-author on the manuscript. The project has received ethics clearance from the external PI's REB.
  - The majority of the board agreed this was a multi-jurisdictional project and should require Brock REB review.
  - The board discussed whether our requirement should differ based on different levels/types of data (e.g., identifiable versus de-identified, sensitive versus benign).
  - The argument that was made by members of the REB sub-committee (GPPC) was that secondary use of de-identified data would require REB review on the basis that it is deidentified. So, would it be fair to not require REB review in the example given above if it is the same "type" of data? The difference in the scenario presented above is that consent has been given for this particular research purpose and the proposition is simply to allow another researcher to have access to the data.
  - A board member pointed out that one of the examples in Chapter 8 of the TCPS2 of research that may require the involvement of multiple REBs in Chapter 8 is "a research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or X-ray technicians, social workers and school teachers)." Would the scenario above be

- synonymous to the "statistician" example given in the TCPS2?
- If a researcher were to look at de-identified data and not be a co-author on the paper, the TCPS2 suggests that REB review is not required but as soon as authorship is added, it would require review. Is this taking participant safety into account?
- GPPC has proposed a set of requirements where Brock REB would be required in a multi-jurisdictional context.
   These were reviewed for the board's consideration:
  - Regardless of study location, Brock REB oversight is required when the Brock researcher:
  - Is part of a research project that has not been approved by another REB
  - Has direct involvement in the project (i.e., recruitment and consent, data collection, analysis/storage of identifiable information), regardless of study location;
  - Holds the research grant or sub grant (regardless of study location or the researcher's specific role);
  - Has a conflict of interest in the project (e.g., financial gain, commercialization);
  - Is conducting the project as part of their academic degree, or supervising the project being conducted as part of an academic degree, regardless of study location.
- The board's discussion today seems to be consistent with what GPPC has proposed in our new requirements.
- Multi-jurisdictional projects where Brock REB is not required seems to be more challenging for us to define:
  - If you are dealing with de-identified or anonymized data, where does this stand?
  - What about scenarios where a researcher requests access to de-identified data that eventually is going to be uploaded in the public domain via Open Science? Does it make sense to require REB review to allow access to data that will eventually become public?
  - Board members discussed that the term "aggregate" in the proposed guideline would not be relevant to a qualitative researcher or a single subject design. This might not be the correct language.
  - Accessing de-identified data after it is collected could be a loophole for researchers to use (i.e., they wait to be involved in the project until after data is collected and de-identified so they are not required to go through REB review).
  - Other board members agreed the word "deidentified" makes more sense (versus aggregate) and keeps with the spirit of the guideline, while also keeping with the push for Open Science.

|   |         | <ul> <li>Board members asked for clarification on the requirement for Brock REB review where a researcher holds the research grant or sub grant. What if you are a co-investigator on a grant or portion of a grant but not directly involved in the project? Should this point specify that the researcher must be the PI on the grant?</li> <li>The Chair explained that the Social Science REB will be discussing these same scenarios at their board meeting next week and we will compile the feedback to take back to GPPC.</li> </ul> |  |
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| 3 | Adjourn | Meeting adjourned at 1:56 p.m.   | Motion to adjourn: KG<br>Seconded: MS<br>All in favour |