

BROCK UNIVERSITY RESEARCH ETHICS BOARD
Friday, October 20, 2017
12:00 – 2:00 p.m.
MC D350-L

Minutes of the BREB Meeting

Attendance

Jean Armitage
 Stephen Cheung
 Stephen Emrich
 Gail Frost
 Kimberley Gammage
 Lara Green
 Grant Hayward

Matthew Mallette
 Jennifer Matunin-Brown
 Sandra Peters
 Maureen Shantz
 Ayda Tekok-Kilic
 Craig Tokuno

Regrets

Kirsten Bott

MINUTES		
ITEM	DISCUSSION	ACTION
1	<p>Motion to approve Agenda</p> <ul style="list-style-type: none"> • Approved <p>Motion to approve September Decision Reports</p> <ul style="list-style-type: none"> • Approved <p>Motion to approve September Minutes</p> <ul style="list-style-type: none"> • Approved 	<p>Motion to approve: ATK Seconded: SC All in favour</p> <p>Motion to approve: MM Seconded: LG All in favour</p> <p>Motion to approve: JA Seconded: JMB All in favour</p>
2	<p>New Business</p> <p>Full board review (in camera)</p> <ul style="list-style-type: none"> • SC excused himself from the review of the first full board file given a conflict of interest. <p>The REB Sub-Committee on Guidelines, Practice, and Procedure (GPP)</p> <ul style="list-style-type: none"> • The new documents to be approved by BREB today were reviewed: <p>1. REB Guideline – Multi-Jurisdictional Research:</p> <ul style="list-style-type: none"> • SREB approved the guideline but asked for the formatting to be fixed, prior to distribution. • The Board discussed multi-institutional agreements. LW indicated that Brock only has two agreements: one with the Ontario Cancer Health Research Ethics Board (OCREB) for a small arm of a clinical trial happening at Brock (the arm at Brock is exercise data and handed into the main study). We have an agreement that the other institution is the board of record and therefore fully responsible for the project, without requiring our review (although that being said, we did look at what they are doing at Brock; ask the researcher for an annual report, and request that they report to Brock any adverse 	<p>Motion to move in camera: SE Seconded: GF All in favour</p> <p>Motion to move out of camera: SC Seconded: SE All in favour</p>

	<p>events).</p> <ul style="list-style-type: none"> • The other agreement is a SSHRC partnership grant which involves 12-13 partner institutions. The agreement with the University of Alberta indicates that Alberta will be responsible for their own projects individually with a local Principal Investigator (PI). • These agreements are made at the institutional level, read by our ethics office and drawn up by our lawyers (they are in a sense, liability agreements). • SREB asked why Brock does not have an agreement with every post-secondary institution in Canada so that our ethics boards can accept each other's approval as reciprocal (and therefore, avoid previously approved applications). • LW explained that most universities do not want these agreements. They feel they should still look at each project that falls under their auspices or jurisdiction. Especially because there are local contextual factors that usually need to be dealt with, which the REBs of other institutions might not be aware of. • The Chair brought the Board's attention to the changes made to this guideline since it came to the REB a few months ago – GPP added a section from the TPCS2 defining multi-jurisdictional research and a summary paragraph in lay language summarizing this Article. This is something that is problematic for compliance cases, so it was made very clear in this paragraph. • A Board member asked: does a researcher need to get clearance from Brock's REB if they are just writing a few paragraphs of the manuscript for example? • LW explained that authorship can only be given if there has been a significant intellectual contribution to the study. If a Brock researcher provides significant contribution, they are considered part of the research team. As part of the team, they become responsible for the project as a whole, including the ethics and data. • If there was a problem with the study, all of the researchers would be at fault, including the researcher at Brock, regardless of their contribution. In other words, even if they only wrote a few paragraphs of the manuscript and did not have anything to do with data collection, analysis or management, the compliance case would still need to be dealt with at Brock given they would be considered part of the team. • Anything that a researcher does under Brock's auspices and jurisdiction, which means using Brock's affiliation, needs to be seen by the Brock REB. • This is particularly relevant in international partnerships because there have been issues in the past of a Brock researcher being associated with a project in another country where ethics is not up to our standards. This also stops researchers from shopping around in other countries to do unethical studies. • A Brock researcher contributing a few paragraphs to the manuscript or helping by interpret the data would fall 	
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		<p>under the following stipulations of the TCPS2 Chapter 8: “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; 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).”</p> <ul style="list-style-type: none"> • A Board member asked whether this would then be considered retroactive clearance – if the data collection is already done and a Brock researcher comes back to Brock for approval to be added to the team. LW clarified that ideally the other REB (the board of record) would file a modification to include the co-investigator from Brock first. • A Board member asked - what if the Brock researcher is just looking at the results (i.e., the complete data, not the raw data)? LW clarified that if the researcher is doing interpretation, this is still research. The way the results are interpreted or written up can be risky e.g., stigmatizing communities etc. • The Chair provided an example of a previous study: data was taken from a hospital in another country and when the Chair reviewed the application, it was not clear whether the patients were aware that their records would be used for research purposes. This may not have been an ethics standard in the other country but in Canada, we have an obligation to follow the TCPS2. • The Chair and Office do our best to complete an expedited review of these previously approved application, so it is a quick turn-around for researchers. • Board members felt that this actually contradicts the push from the Tri-Council to make data available to others (for transparency, replication purposes, validation etc.). • LW agreed there might be a better system for reviewing these applications to ensure this is an easier route for researchers however, at this point, we have an obligation to follow the TCPS2. • LW indicated she has gone to the Secretariat and asked about this before (given it is not practical for researchers in practice). The rationale is that even if you are just writing, if there was an issue with the study, it is still your study and therefore, your issue. • The dissemination in the end is the culmination of the project and does not allow for separation of one collaborator from the others. For example, a statistician who just ran the stats – if there was a compliance case, the statistician would still be considered part of the team. • Board members asked how open access data will fit into this? LW indicated that the concept is not totally 	
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	<p>developed yet. By 2018 though, researchers will need to come to the REB with their plans for making the data public (e.g., in what form etc.).</p> <ul style="list-style-type: none"> • We can guess that for the short term, secondary use of data applications would allow for access to anonymous or anonymized data in these open access data banks. • The Chair provided an example of a recent study using genetic testing where they planned to purchase samples from a biobank. This biobank stores de-identified samples that were collected ethically and when they sell the samples, they never divulge the participant information to researchers. This would be an example of where open access data might be headed. • A member asked: if a post-doc left their previous institution and came to Brock, do they need Brock clearance? LW clarified that typically researchers publish under their affiliation where most of the work was done. So, if the majority of research was done at the other institution, they would publish under that affiliation and would not require our clearance. However, if the research is still continuing or plan to publish with their Brock affiliation, they would require ethics clearance here. It was noted that this would still be a previously approved application though and would not require the full application to Brock – the previously approved application is an expedited review and a very quick turn-around for researchers. • Members commented that some journals ask for the “affiliation of the author at the time the research was conducted.” This might help the post-doc mentioned above make this decision. • Motion to approve put forward by KG, seconded by JMB. Majority vote to approve the guideline (10 voted in favour, 2 abstained). • LW will take these concerns back to the Secretariat and say this is causing a lot of problems on the ground. <p>2. REB Guideline – Continuity During Unforeseen Circumstances:</p> <ul style="list-style-type: none"> • SREB approved this guideline. • However, the Office noticed that continuity of research should be left up to the Vice-President of Research (VPR), which is not consistent with what is written in this guideline. • Guideline will go back to GPP and we will confirm with the VPR that it is up to the institution to determine whether research can continue in an emergency situation/pandemic. <p>3. REB Standard – Minor and Substantive Changes:</p> <ul style="list-style-type: none"> • It was explained that SREB requested more examples be included under minor changes. One SREB member volunteered to craft more examples of minor changes that can be included. • For example, just updating an instrument from one 	
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		<p>original version to an updated version – would this be considered a minor or substantive change?</p> <ul style="list-style-type: none"> • It was explained that SREB members also discussed whether this system is setting up an unfair advantage to emergent research like grounded theory and ethnography. The Board allows those methodologies to be explained with a lot of space. Are we disadvantaging people with strict, structured measures saying you have to tell the Board and wait for approval for every single change, but the emergent researchers do not need to? • This document also leaves the judgment of whether a change is minor or substantive up to the researchers. Will all researchers gauge and interpret the guideline equally to ensure we do not encounter cases of non-compliance? • The Board asked that this guideline go back to GPP to work out these final details. 	
3	Adjourn	Meeting adjourned at 1:57 p.m.	Motion to adjourn: CT Seconded: SE All in favour