BROCK UNIVERSITY RESEARCH ETHICS BOARD
Wednesday, November 14, 2018
12:00 – 2:00 p.m.
MC D350-L

Minutes of the SREB Meeting

Attendance		**Regrets**
Michael Ashton	Trent Newmeyer	Sandra Bosacki
Kirsten Haylow	Thomas O'Neill	Lynn Dempsey
Caitlin Kelley	Robert Steinbauer	Catherine Nash
Carly MaGee (non-voting)	Christine Tardif-Williams	Kendra Thomson
Linda Morrice	Amber-Lee Varadi	Xiaoyang Xia
Miya Narushima	Lori Walker (non-voting)	

MINUTES			
ITEM		**DISCUSSION**	**ACTION**
1	**Motion to approve Agenda** • LW added the following to the agenda: feedback/complaints received. • Approved **Motion to approve September & October Decision Reports** • Approved **Motion to approve September Minutes** • Approved		Motion to approve: CTW Seconded: MA All in favour Motion to approve: LM Seconded: TO All in favour Motion to approve: TN Seconded: CTW All in favour
2	**Business Item**	**<u>Introduction of new members</u>**	
3	**Education Items**	**<u>Discussion on article "When Good Intentions Backfire: University Research Ethics Review and the Intimate Lives of People Labeled with Intellectual Disabilities"</u>** • Board members were asked to read the above article and bring any discussion points to the meeting today. The article critically discussed how the authors felt that practices of ethical governance through university research ethics committees can contribute to the silencing of people labeled with intellectual disabilities through the reproduction of discourses of vulnerability and protectionism. • The Chair pointed out that the information relates well to Chapter 4 of the TCPS2 pertaining to fairness and equity in research participation (addresses inclusion in research of individuals and groups that might be inappropriately excluded on the basis of attributes such as culture, language, gender, race, ethnicity, age and disability). • The article pointed out that in some cases, it seems as though REBs are trying to protect the institution (instead	

		of the participants) which is outside of the REB's mandate ("We all know that the primary mandate of IRBs is—first and foremost—to protect study participants. However, in this climate of fear coupled with extreme 'administrative constipation', many investigators wondered aloud if the true hierarchy was protection of (a) self [the IRB], (b) the institution, (c) the participant, and (d) the investigator [in that order]"). • LW mentioned how this article ties in nicely with a recent survey request that came to our office: Michigan University requested to administer The Healthy Minds Study (HMS) to our Brock students; an annual web-based survey study examining mental health, service utilization, and related issues among undergraduate and graduate students. However, in the United States those under the age of 18 are not permitted to participate in research without a waiver of parental consent. As such, we requested that Brock students under the age of 18 be eligible to participate given that is our local guideline and would avoid unnecessarily silencing the voices of others based on their demographic criteria. Further, our REB was concerned with the exclusion of Brock students under the age of 18 as knowledge gained from this research could be pertinent to this group, particularly in planning supports on campus. A segment of our student population would be excluded, and we strongly suggested to the lead researchers of this project that Brock's arm of the study find a way to give voice to our younger students. • We felt this was a compromise and opportunity to ensure all the participants were protected while not unjustly excluding any group. • In this particular case it was a tricky position between the US and Canada systems (i.e., US IRBs are legislated so they could not change their guidelines to include students under the age of 18. Instead we strongly recommended and suggested that they find some sort of compliment in the results [testing those under 18 in a later study for example for comparison purposes]). • It is our responsibility as the REB to include these populations in order to extend knowledge (which is part of the definition of research in the TCPS2). This is very similar to the sentiments in the article pertaining to research with those with intellectual disabilities. Is there justification for excluding these individuals in research? We need to think about (and ask our researchers to think about) whether we are unjustly excluding people from research opportunities. • The Chair encouraged the board to think about the fact that there are degrees of disability too. An individual with a disability does not automatically mean they do not have the capacity to consent or make decisions on their own. The REB needs to ensure we are not automatically labelling disability with lacking capacity to make	

		decisions. It is not a one size fits all approach and each study and population needs to be considered uniquely and according to the context of the research (while considering the welfare of the participants). • The article focused a great deal on risk and vulnerability indicating that individuals labelled with intellectual disabilities should be included in minimal or less than minimal risk studies with appropriate scrutiny from REBs, and that they should also be included in greater than minimal risk studies with greater scrutiny from REBs (as in any greater than minimal risk study that would be reviewed by our full board). • The community member on the board pointed out however that there may be scientific or methodological reasons for excluding individuals with intellectual disabilities. For example, if the researcher is implementing a Randomized Control Trial (RCT) and it has not been tested in populations with disabilities, the researchers have to adhere to the standards of the research and the integrity of the program. Similarly, in cases where individuals have a dual diagnosis, it is possible this may cloud the results of the research and lead to inappropriate interpretation/application of findings. • The Chair summarized a few important points for the REB to consider (and were mimicked in the article): o That it is inappropriate to assume participants cannot consent on their own. Are there other mechanisms of consent (other than written) that can still respect the autonomy of participants? As the REB, we need to understand these possibilities and push the researchers to think about this - what sort of accommodations can you make? (without automatically assuming the participants cannot consent or blanketing the consent mechanisms for all participants). o Consider the appropriateness of "feedback questions" (which are often used as a part of the consent process to ensure adequate understanding and comprehension where after every paragraph, the researcher asks the participant a question about what they were just told). The authors pointed out that they believed this method was working well and respected the autonomy of the participant until they had one participant say they were offended by this approach because it was not appropriate for him and his individual capacity. This was a reminder to the researchers that everyone is an individual and researchers can not rely on a one size fits all approach; the consent process should be altered and adapted to the needs, capabilities and competencies of each individual participant. o LW pointed out how the new version of the TCPS2 focus on *research attributable* risk. Understanding that anyone can move in and out	

		of vulnerability at any point in time and if the risk exists for that population already (and the research does not impose any *additional* risk), the researcher (and the REB) do not have to take responsibility for risk that inherently exists in the participants life (but is unrelated to the research). We are only accountable for the risk associated with the research specifically. E.g., asking a suicidal population survey questions does not increase their vulnerability or comprise their safety. As such, we should not be limiting researchers' ability to work with these populations. ○ The article pointed out how the "infantilization of research participants, especially those deemed 'vulnerable,' can sometimes lead to forms of protectionism that take precedence over participants' agency, including their right to make their own decisions, share their own perspectives, and take informed risks. In other words, the label of 'vulnerable' (irrespective of which group it is applied to) can—intentionally or otherwise—lead to the disempowerment of research participants." REBs need to ensure they are enacting within their role, and not taking on this protectionism approach. • A board member felt that Section 5 of the article pertaining to shaping relationships with participants was the most useful (given the practical versus ideologic nature of this section compared to others). Although, the board disagreed with some of the perspectives of the authors (e.g., that you cannot subscribe to the medical model and still abide by the "nothing about us without us" approach to research). Do we have to have a critical disability lens in order to treat participants ethically? • The article pointed out that REBs "need to be educated on disablism as a way of moving beyond individualizing and pathologizing medical models of disability that can deny the agency of people with intellectual disabilities, and that promote a view of people with disabilities as only their diagnosis, and thus, not able." Board members disagreed slightly and felt that bringing a protocol to full board can be part of the education process – can researchers help the REB with this education piece? Given that membership changes every year (or every other year), REBs are constituted by different people on a continual basis. It would be helpful if researchers saw the protocol process as a dialogue to help educate new members about areas of research we are not familiar with, advancements in the field, effective strategies, expertise and experience etc. • Board members felt that we need to highlight that there is a communication channel between researchers and the board; it is not a top down approach with REBs telling researchers what they can and cannot do. In fact, this is why we invite researchers to come speak at full	

		board reviews – in an attempt to open up this conversation. That open dialogue is important on the researcher side as well, so they know the board is undergoing training in order to evolve and better facilitate research at the university. • Another point in the article was that graduate students might not have the agency or feel comfortable opening up the conversation with the REB in the same way that a faculty member might (for graduate research for example). In these cases, we rely on the faculty supervisor to facilitate this process for the student. • We have found that in-person conversations are much more fruitful, conversational and productive so we try to promote those to researchers when we think it might be helpful (sometimes just the office and the researchers – the board might not be involved). As a REB, we need to remember that it is our intention to facilitate research, not shape it. As such, we can tell researchers about our grounding principles under which we are expected to make decisions (the TCPS2) and the researchers can come back with their knowledge of the field, their interpretation, and how the project might be best carried out to ensure compliance to the TCPS2 as well as fulfilling the goals of the researcher. • A board member summarized that a great deal of the article was surrounded around frustration with the REB; particularly researchers are frustrated with being asked by the REB to justify and explain their expertise. This has happened at Brock as well and some researchers find this insulting. LW clarified that if our office were to be audited, one random file would be pulled. So, we require record of the expertise of the Principal Investigator (PI; where appropriate) on every file, versus the REB and office just assuming from previous files that the same expertise applies. Although it may seem repetitive, it is necessary to ensure our compliance and due diligence. It may also be a point of education for researchers – to inform them that because our REB has a rotating membership, not everyone on the board will be familiar with a particular researcher's scope of work, history with the REB or expertise. If researchers are able to embed this into their applications up front, the REB would not have to ask this in subsequent clarifications/revisions and perhaps this may diffuse the feelings of insult on the part of the researchers. • LW pointed out that some REBs require researchers to attach their CV to each submission. We are not asking for such depth, but it is fair to have information regarding expertise on record where the project permits (i.e., if it is a project that requires very specific expertise etc.). • Board members felt that a preamble around this request (for expertise) might be helpful to contextualize it (e.g., this is why we are asking this question). • LW anticipates these issues being resolved we launch our new form because the questions are designed to	

		deal with these questions upfront, in the writing stages (i.e., the researchers are prompted to include the information at the outset which avoids the REB having to ask the question over and over). Our more precisely targeted application form will catch these requests/responses ahead of time. Further, the new application will be smart form and have information "bubbles" to assist our researchers in writing a more comprehensive application. • The board talked about strategies for how we can change our tone (in clarification/revision requests) to be more conversational. • We are working towards this by putting more pointed statements in notes, and accepting the project as is (with those notes). E.g., if there are some details that are missing from the consent form. We will accept the project with notes (to send back a revised form when the changes are made) as opposed to sending back a clarification and revision request for these less formal and less conversational pieces (which is perceived as less of a hurdle for researchers). • The board talked about whether it would be helpful to separate clarification points into important issues versus minor issues (similar to the publication process). Would this "brighten the mood?" The minor issues would still need to be commented on but there is more room for discussion and may help distinguish requirements from conversations. • Some board members felt this might confuse researchers into thinking the major issues are ethical concerns and the minor are our opinions. • Members debated citing the TCPS2 for all major points, so researchers can see where the comment is grounded in. However, this would lengthen the request form (which researchers may not like). • But how can we make sure people know there is open conversation? Should we put a note on the clarification/revision request explaining this? Board members liked this idea (so researchers know they have the opportunity to contact us and reach out). • LW suggested bringing the new application back to the board for a 2-hour meeting for another read through to ensure we are helping researchers write more comprehensive applications, resulting in fewer clarification/revision requests on the back end. **<u>Q & A: Discuss questions brought forward by board members re: reviews, ethics, processes, procedures etc.</u>** • A board member thought it would be helpful to have the consent form in a more condensed format (e.g., bullet points). Perhaps including an alternate template on the website and ensuring that researchers know they are not required to follow the template (it is just a guide). Perhaps we should consider creating a consent manual	

		of sorts (e.g., provided you hit the key points, here are a couple of examples). • This will be taken back to the REB subcommittee – to improve our resources around consent. **Feedback/Complaints Recieved** • LW summarized two points of feedback that have come to our office recently. One pertains to the mandatory reporting law statement. The REB requests that this statement be put on the consent form for any research taking place in a participant's home. Most recently, we requested that this statement be included in a study examining experiences of White Canadian women in Transnational, Transcultural relationships with Black men in the Caribbean, where the researcher planned to interview participants in their homes. Our current stand on research in participant homes is that any research taking place in a participant's home presents opportunity for the researcher to witness (and therefore be under legal duty to report) risks related to abuse/harm. We ask researchers to inform participants that they are under obligation to follow mandatory reporting laws, meaning if the participant discloses or the researcher views any child abuse, the researcher must by law report it to child protective services. We also ask for this information to appear in the consent form. • We had push-back from the researcher on this particular file indicating that this comment would be interpreted by prospective research participants as being racist and could scare participants away from participating at all, given the comment is not relevant to the research (they are not interviewing about child abuse, and some of the participants may not even have children). • As a result, LW did a call around to different REBs around the country and all surveyed REBs indicated they are only using this statement in cases where the research could foreseeably bring up instances of child abuse/neglect. Originally it had been our REB procedure to include this statement in any research where the researcher was entering into a participant's home because it limits the confidentiality of the participant (more intrusive then meeting them in the lab). However, perhaps we can instead request that researchers include a statement about limited privacy/confidentiality in general, without specifically pointing to child abuse. • Mandatory reporting laws stand regardless of whether we tell participants or not, and regardless of where the research takes place. However, it was a decision of the board years ago that there is *increased* opportunity for the researcher to witness (and therefore be under legal duty to report) risks related to abuse/harm when entering the participant's home (and we are obligated to inform participants about any limitations to their confidentiality in a research context in the consent form). However, board members could also understand how it	

		might be frightening for participants to read this statement – particularly in studies that do not pertain to children or there is no foreseeable reason why child abuse may arise in the course of the research conversation. • A board member agreed that by putting this statement in consent forms, it might give participants the idea that we suspect there might be something going on, which could cause people to walk away from the research if they are scared. This researcher has found this to be a particular hurdle when conducting research in Nepal (where people are already scared to sign a form). • The board agreed that the spirit of the message (originally) was that are different privacy issues when conducting research in a participant's home. As such, the board agreed the statement pertaining to mandatory reporting laws (specifically, child abuse/neglect) should only be used in research where there is a conceivable possibility of child abuse/neglect being revealed through research conversation, e.g., research with kids who play hockey and are asked questions about how their coaches treat them etc. We plan to look at studies on a case by case basis and request that the child abuse statement be included where we think it is truly reasonable for child abuse/neglect to come up. • The board asked that the REB subcommittee craft statements that cover limits to privacy and confidentiality when researching in the home (without mention of mandatory reporting laws; simply to bring light to limits to privacy). In other words, a statement that informs participants that the choice to allow researchers into their homes inherently limits their privacy and confidentiality. The board agreed however that the mandatory reporting law statement currently used should not be automatically requested for any research that takes place in a participant's home *(unless* the research is on child abuse or there is reason to believe instances of child abuse may be revealed during the research). • LW summarized the second piece of feedback received by our office pertaining to random digit dialing: the SREB recently approved a project using random digit dialing, and the researcher is now receiving a great deal of feedback from participants (e.g., how did you get my number? Particularly for those on a "no-call" list). To remediate these concerns, the researcher began including a statement in the opening preamble of the study indicating that the participant had been contacted through random digit dialing and that they can be removed from the call list if they wish. • The board wondered though – is being "cold-called" within the realm of everyday risk? • The researcher also pointed out that publishers have critiqued her previous research indicating that her samples are not representative enough, so she was	

		using random digit dialing as a way to obtain a more representative sample. • The board agreed that participants may be feeling irritated, but it is not over and above everyday risk. • The board wondered about whether a different platform could be used to reach participants (e.g., social media) however, this would bias the sample of participants obtained. • Several participants also contacted the PI wondering whether or not this was legitimate research. To remediate these concerns, the researcher has adapted the introduction to explain (at the beginning before people hand up) that a professor from Brock University is conducting the research (as opposed to saying "x company is doing this research etc."). • LW confirmed that the company is not collecting any data from the participants. • Members wondered whether the researcher is excluding people on no call lists. It was thought that the company may have a no call list for their particular company (not a universal no call list). So, it may be an option to add people who do not want to be contacted by this company to the "company" no call list (but that it would be unlikely to have a universal no call list that would guarantee someone never gets called by anyone). • The board felt that people may just be overly cautious because of all the phone scams these days, but agreed that this risk is within everyday life, and is no riskier than someone recruiting on the street (which we also approve through the REB). Further, since the company will not be re-calling anyone (one call to each phone number only), participants should not feel "pestered."	
4	**Adjourn**	**Meeting adjourned at 1:53 p.m.**	Motion to adjourn: MA Seconded: CTW All in favour