BROCK UNIVERSITY RESEARCH ETHICS BOARD Thursday, November 30, 2017 12:00 – 2:00 p.m. MC D350-L

Minutes of the SREB Meeting

Attendance

Michael Ashton Lynn Dempsey Ann-Marie DiBiase James Foley Karen Julien Linda Morrice Catherine Nash Robert Steinbauer Kendra Thomson Regrets

Sandra Bosacki
Christina Garchinski
Miya Narushima
Mary-Beth Raddon
Esther Santos
Christine Tardif-Williams

MINUTES ITEM DISCUSSION ACTION Motion to approve Agenda Motion to approve: RS Seconded: CN Approved All in favour **Motion to approve October Decision Reports** Motion to approve: KJ Seconded: CN Approved All in favour Motion to approve: LM **Motion to approve October Minutes** Seconded: RS Approved All in favour LD abstained due to absence at the last meeting. **New Business** The REB Sub-Committee on Guidelines, Practice, and Procedure (GPP) The new documents to be approved by SREB today were reviewed: REB Guideline – Continuity During Unforeseen Circumstances: The SREB approved this guideline at the October meeting. However, after the meeting, the Office noticed that continuity of research should be left up to the Vice-Present of Research (VPR), which is not consistent with what was written in this guideline. Guideline went back to GPP and we confirmed with the VPR that it is up to the institution to determine whether research can continue in an emergency situation/pandemic. It was also clarified in the document that research activities may continue with caution under the following circumstances: 1) the emergency or pandemic does not impose any additional threat to participant safety or comfort (e.g., exposure to communicable disease, dangers accessing the research location, etc.); 2) the

- required support services necessary for participant safety are available to respond (e.g., campus security, lab support staff, etc.); 3) where ceasing activity may pose a risk to participant safety or otherwise negatively affect the risk-benefit ratio.
- GPP felt it was important to note in this guideline that even if the research is not taking place anywhere near the emergency situation, researchers should consider whether appropriate campus support would be preoccupied with the emergency and therefore, unavailable to the researchers should anything happen (i.e., campus security tied up with a fire alarm on one end of campus and testing occurs at the other end where no alarms have been sounded. Even though research could still technically continue, researchers need to think about the fact that campus security would be tied up with the fire and unable to be of assistance to the researchers in the event they needed them).
- All Board members agreed the changes were helpful in improving the document.

REB Standard – Minor and Substantive Changes:

- At the last meeting, SREB requested more examples be included under minor changes. One Board member volunteered to craft more examples of minor changes. This supplementary document of examples was circulated to Board members prior to the meeting today to facilitate discussion.
- The supplementary document proposed the following: In many research studies, participants complete questionnaires whose scales consist of items having a multi-point ("Likert") scale response format. Those questionnaire scales assess various psychological characteristics. Often a researcher will wish to replace or supplement an existing set of questionnaire scales (whose use in the project has already been cleared by the REB) with one or more additional questionnaire scales. In some situations, a researcher will need to submit a modification request for the current project, but in other situations, the researcher can add the new questionnaire scales without a modification request, as long as he or she notifies the REB at the time of the addition. This document is intended as a guideline for distinguishing between the above situations. One principle underlying this guideline involves the level of "risk" associated with the questionnaire scales. Another principle involves the volume of the changes and the extent to which they change the focus of the research. Regarding the first principle, the document outlined examples of constructs that fall under two different categories, with differentiation according to the level of risk involved (e.g., Category A - personality characteristics versus Category B – suicidal ideation and self-harming behaviours).
- The Board discussed how we would need to work

- together to determine what topics would be considered Category A ("benign" or minimal risk). This supplementary document could be framed around structured instruments but may apply to other formats as well.
- Members felt this would be a reasonable proposition.
 However, what if the addition of questionnaires
 significantly increases the time commitment associated
 with participation? The Office explained that we included
 the word "comfort" in the current guideline to capture
 this (i.e., "Minor changes are adjustments or refinements
 to research that do not elevate risk or affect participant
 safety, <u>comfort</u>, privacy, or confidentiality").
- CM asked the Board: Does the word comfort capture significant increases in time commitment? Members wondered whether we could include time commitment as an example in brackets after the word "comfort" to make this clear to researchers.
- A Board member felt that if the proposed modification does not change the description of the study in the consent form, and does not elevate risk or affect participant safety, comfort, privacy, or confidentiality it should not require a formal modification request. For example, if the consent form indicates participation will involve answering questions about sexuality and political views, and the researcher wishes to add a 10-item inventory on personality characteristics (which does not elevate risk or affect participant safety, comfort, privacy, or confidentiality), they should not require a formal modification request form.
- The member who crafted this supplementary document tried to capture this "rule of thumb" throughout each of the case studies provided (i.e., that whenever researchers are adding or exchanging questionnaires which do not elevate risk or affect participant safety, comfort, privacy, or confidentiality, they simply need to alert the Office, but do not need to submit a formal modification request. But if researchers are adding or exchanging questionnaires which elevate risk or affect participant safety, comfort, privacy, or confidentiality, they are required to submit a modification request to the Office and wait for approval; even if they are just swapping out one questionnaire for another of the same construct. If it is a sensitive topic, it needs to be submitted as a modification request).
- Board members discussed whether the issue is timely notification versus what changes require a modification request. If researchers email the Office right away and let us know of the change they intend to implement, we could stop it from advancing if we felt it was substantial and required a form. Could requiring immediate notification combined with the guidelines address our concerns?
- Members pointed out that this method would download a lot of responsibility to the office – how do we feel

about this?

- A Board member asked whether we have ever encountered a minor change listed on an annual report that should have been filed as a substantive change? If not, is this even a problem we need to address? Should we even be asking for this immediate email notification if this would simply be adding more work for the Office without improving processes?
- Members agreed though that if we are going to expand the definition of what is considered a minor change, we need to have protective processes in place to make sure researchers are not moving ahead with changes that should be submitted as substantive. That is why immediate report to the Office might be necessary.
- The Board discussed whether the following change would be considered minor or substantive: Measures of any construct type within category (A; do not elevate risk or affect participant safety, comfort, privacy, or confidentiality) are to be replaced or supplemented with measures of the same construct type within category (A).
- The Board felt this change could be considered minor however, should require immediate report to the Office (in email format). The purpose of these email notifications would be to give the Office a description of the minor change to be added to their folder, and would que any red flags if they submitted it as a minor change and we think it should be substantive. The Board's suggestion was to have specific criteria around how researchers should submit a minor change via email e.g., with a certain subject heading that we decide on, so we can efficiently sort through these. A member suggested that the Office could set up a separate folder in the email account to drop these "FYIs" and sort through them after higher priority items are taken care of.
- Other members in the room felt this proposition would also extend to their work in Applied Behaviour Analysis (ABA; using certain techniques and principles to bring about change in behaviour, often used with those with autism). For example, they indicated that sometimes when they are conducting ABA, the environment changes (child's situation changes, they are put on/taken off medication etc.). Because of this, they have to alter their measurements to adapt. These members felt that changing the guideline to allow instruments measuring the same construct to be swapped out that have no additional risk to participant's safety, confidentiality, privacy or comfort; aligns with what the participant consented to; and more appropriately measures the construct (given the changes in environment that occurred), would facilitate these changes to their research as well.
- It was also suggested that a flow chart might be helpful for researchers (similar to the cases: "did you change an

- instrument under category A that measures the same construct, does not impact participant's safety, confidentiality, privacy or comfort and also aligns with what they agreed to in the consent form? If yes... if no...etc."). However, the Board agreed that it would be impossible to incorporate all disciplines into one chart.
- The Board agreed that if we went forward with the proposed changes to the document (included in the supplementary document discussed today), the website would need to include some helpful resources to assist researchers in making the judgment about whether their proposed change is minor or substantive.
- Board members felt that this system would solve the problem of the potentially unfair advantage our current guideline sets up for emergent research (i.e., we currently allow those methodologies to be explained with a lot of space but ask researchers with strict, structured measures to tell the Board and wait for approval for every single change).

Discussion

Should <u>Guidelines for Research Participation of Individuals</u> <u>Under Age 18</u> be extended to all university students?

- Our current guideline states that consent from a parent or guardian is not required for research participation of *Brock University* students under the age of 18. However, we accept requests for waivers of parental consent for minors not attending Brock on a case-to-case basis. This means that when researchers are collecting data from students at other post-secondary institutions (nationally and internationally), we them to provide justification for why they are not collecting parental consent, should the students be under 18.
- Members of SREB encouraged the office to take a scan of how other REBs in Canada are handling these situations, as our current practice might not be the most efficient or logical set-up (that we have assumed Brock students under 18 have the autonomy to make these decisions on their own but that other university students under 18 may not).
- Members suggested that our current guideline could be altered to allow any post-secondary student to provide their own consent.
- However, a member pointed out that places like Niagara College offer dual credits (Ministryapproved programs that allow students, while they are still in secondary school, to take college courses that count towards their certificate/diploma, or degree), which would mean we could potentially start sampling secondary school students without parental consent as well (perhaps not the answer to our problem).
- Members talked about whether our new guideline would extend to all post-secondary students or whether we

		 would restrict this to those attending a post-secondary school in Canada. A member suggested altering the guideline to indicate that consent from a parent or guardian is not required for research participation of full-time university/college students. However, this would eliminate part-time students who may also have the autonomy to make these decisions on their own. CM agreed to reach out to other REBs in Canada to inquire about their policies around this. 	
3	Adjourn	Meeting adjourned at 1:20 p.m.	Motion to adjourn: KT Seconded: LM All in favour