BROCK UNIVERSITY RESEARCH ETHICS BOARD
Wednesday, October 19, 2016
12:00 – 2:00 p.m.
MC D350-L

Minutes of the SREB Meeting

Attendance
Lynn Dempsey
Jan Frijters
Christina Garchinski
Mahfuz Hassan
Karen Julien
Christine Tardif-Williams

Regrets
Sandra Bosacki
Miya Narushima
Bill Helmeczi

MINUTES			
ITEM		**DISCUSSION**	**ACTION**
1	**Motion to approve Agenda** • Tabled as meeting did not meet quorum **Motion to approve September Decision Reports** • Tabled as meeting did not meet quorum **Motion to approve September Minutes** • Tabled as meeting did not meet quorum		
2	**Updates/Follow-Up**	**Compliance Case** (In camera)	Motion to move in camera: MH Seconded: MN All in favour
3	**Business Items**	**Policy & Guidelines Committee** • L. Walker indicated that last year the Research Ethics Office (REO) called for the development of REB sub-committees. These committees would tackle one working procedure/item on the agenda each meeting. However, this approach did not prove successful and it was difficult to retain attendance and commitment from members. The office intends to take on a different approach this time around to ensure policies are developed and implemented. • Some examples of policies this committee might establish were provided: who can be a Principal Investigator (PI), guidelines for instructors who are conducting research on their students, creating the new application, guidelines around research with children etc. L. Walker invited board members to spread the word about the committee to others (outside of the REB as well) to gain membership. • L. Walker asked board members to let the REO know if they are interested in being part of the committee. She anticipates this committee will meet once a month and the rest of the time work via email (the REO would provide frameworks or outlines for members to work from).	

		• The array of specialities of board members would assist in developing the most balanced policies with relevant considerations. • Board members inquired about whether the committee would consider developing policy and guidelines around medical trials/clinical trials. L. Walker indicated that once the proposed changes to the TCPS2 are established and finalized (as they address this type of research), this would be an option. • L. Walker confirmed that individuals do not have to be on the REB to be a member of this committee. • Anything this committee develops that is deemed to be policy would be put back to Senate for approval – anything guideline related would go back through the REBs for approval. The REB would hold the final say as to whether the products are acceptable documents. **Update on Appointment** • L. Walker confirmed that all members were officially appointed at the last Senate meeting. The community member's name was accepted to go forward to Senate at the next meeting. Everyone else was accepted at Senate at the last meeting. • L. Walker informed the board that we currently do not have a Chair of the SREB starting in January. Senate is better understanding their role in the recruitment and selection of a new Chair however, there does not appear to be a no clear plan about how a new Chair will be acquired. • L. Walker indicated that in the past, REB Appointment letters came from the VPRs office. However, given that these processes must now go through Senate, we are unclear about who will be responsible for the letters. The Chair noted that should a REB member require the letter to provide proof of workload standards, they could use the Senate minutes (these would have record of members being formally accepted). **CAREB-ACCER VREB Discussion** • The Canadian Association of Research Ethics Boards (CAREB-ACCER) is a national organization dedicated to promoting human participant protection in research and represent research ethics professional administrators. They promote the professionalism of research ethics board administrators and members (collectively referred to as REB professionals) through the sharing of expertise, experience, information and knowledge; represent and communicate the perspectives and concerns of REB professionals in local, national and international policy development and implementation; increase the visibility of the REB's mandate, and advocate for the appropriate allocation of resources needed to ensure the fulfillment of this mandate, including adequate research ethics review and protection of research participants; and provide education and resources needed to successfully promote the ethical conduct of research in Canada. The virtual REB is a new CAREB-ACCER professional development initiative that will facilitate discussion on a series of case studies. These cases have been designed to highlight a range of common ethical issues typically found in human research applications. The first case has already been posted and is	

available to anyone in the public (the next cases will only be available to paying members of CAREB). This provides members with an opportunity to contribute their thoughts on the ethical issues they see in the cases and provide recommendations on how they think the issues should be addressed in REB feedback. A group of Virtual REB Analysts, comprised of volunteer members selected from the CAREB-ACCER community, will review the comments submitted, add their own thoughts, and prepare a case de-brief that will include references to the TCPS2 and other relevant legal and regulatory guidelines. The final case debrief will be made available before the next case is posted. The resulting collaborative product will be archived as a resource which can be used in the training of REB members and professionals. In the future, these can be used for new member training sessions.

- The REO agreed to circulate the link for the virtual REB case and encouraged all members to participate. The first case will be the only one available to the public. Beyond this first case, the tool will be available to members only.

Presentation on proposed changes to the TCPS2

- In keeping with its mandate to ensure that the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans is a living document; the Panel on Research Ethics is proposing revisions to TCPS 2 (2014). The Panel has released these proposed revisions for public comment. Written comments on the proposed revisions to the Policy will be accepted until January 31, 2017.
- L. Walker indicated that an overview/highlight of the changes will be discussed at the meeting today however, a larger training session will occur if the changes are passed.
- Changes in Terminology: certain terms have been revised throughout the text, such as “individuals in vulnerable circumstances” being changed to “individuals whose circumstances may make them vulnerable in the context of research.”
- L. Walker provided an example of research studying participants with spinal cord injury. These individuals are not necessarily vulnerable simply because of their injury – this will be considered in the proposed changes.
- Chapter 2 – Scope and Approach: 1. Define “pilot studies” and emphasize the requirement for REB review, 2. Clarify the different types of observational research, introducing a description of epidemiological studies, 3. Add new article that exempts course-based research activities intended solely for pedagogical purposes from REB review, 4. Add guidance on research-attributable risks and research benefit misconception, 5. Introduce new guidance addressing research involving communities.
- L. Walker indicated that pilot studies do not have to expect the same level of statistical significance. Pilot studies are normally smaller versions of the primary study (e.g., fewer participants, shorter duration). For the purposes of this Policy pilot studies do not include the pre-testing of a research instrument such as a questionnaire. The purpose of a pilot study is to assess the feasibility and/or inform the design of a subsequent study intended to address a research question. They are not intended to produce

		definitive results regarding the research question but they can facilitate the successful conduct of the primary study. For example, pilot studies can help identify recruitment issues, safety issues, the need to calibrate measures, adjust equipment, or improve procedures. The information provided may assist the researcher to decide whether and how to conduct the primary study. The design of pilot studies and the criteria used to determine feasibility may vary by discipline. • Chapter 3 – The Consent Process: Introduce recruitment as a step in the consent process. Consent is a process that typically starts with recruitment. Recruitment is the seeking out of individuals, groups or communities that meet the inclusion criteria of a study. The applications we have received recently have been vague in the recruitment strategy (e.g., word of mouth). More weight will be put on this in the future to ensure a fair and equitable recruitment process is being used based on inclusion and exclusion criteria that are justified by the research question. • Chapter 4 – Fairness and Equity in Research Participation: Introduce new guidance emphasizing the requirement to disseminate research. Researchers shall disseminate, through publication or otherwise, the analysis of data and interpretation of research results including those that do not support the research hypotheses. The dissemination shall take place in a timely manner without undue restriction. Providing a summary of research results to participants is as important as dissemination to the research community (Equitable Distribution of Research Benefits, Chapter 4). To justify the involvement of participants, and the risks and other burdens they are asked to bear, research must be valuable. That is, it must have a reasonable likelihood of promoting social good. If research findings are not disseminated (e.g., published in a peer-reviewed journal, added to a publicly available database, posted on a website, a public presentation) within a reasonable time, their value may be diminished or lost, betraying the contributions and sacrifices of participants. For this reason, and based on respect for participant expectations and protection of the public good, researchers, REBs and institutions have an ethical responsibility to make reasonable efforts to publicly disseminate research findings in a timely manner and without undue restriction. • L. Walker indicated that in the future, the board can discuss whether we want the onus to be on the researchers to provide feedback to participants (or whether we can ask participants to contact the researchers if they are interested). For example, a sample of elderly participants may not have access to a computer to request the results; this may not be feasible for them. In this case, how will researchers ensure participants gain access to the results? • Chapter 5 – Privacy and Confidentiality: Integrate into Policy guidance an interpretation on institutional support for researchers in withholding their ethical duty of confidentiality. For example, in exceptional and compelling circumstances, researchers may be subject to obligations to report information to authorities to protect the health, life or safety of a participant, or a third party, a community or the general population. Researchers are expected to be aware of ethical codes (such as professional codes of conduct) or laws (e.g., those requiring the reporting of children in need of protection or the presence of reportable communicable diseases)	

		that may require disclosure of information they obtain in a research context. In other situations, a third party may seek access to information obtained and/or created in confidence in a research context. In other situations, a third party may seek access to information obtained and/or created in confidence in a research context. An access request may seek voluntary disclosure of information, or may seek to compel disclosure through force of law (e.g., by subpoena). Chapter 1, Section C, elaborates on the relationship between research ethics and law. Where possible, practicable and appropriate, researchers should design their research to avoid or mitigate foreseeable conflicts, e.g., by collecting the minimal identifiable information that is necessary to answer the research question. Researchers shall maintain their promise of confidentiality to participants within the extent permitted by ethical principles and/or law. This may involve resisting requests for access, such as opposing court applications seeking disclosure. Researchers' conduct in such situations should be assessed on a case-by-case basis and guided by consultation with colleagues, any relevant professional body, the REB and/or legal counsel. • Chapter 6 – Governance of Research Ethics Review: Introduce new guidance on the review of sponsor-researcher contracts. • Chapter 7 – Conflicts of Interest: Add guidance on the role of the REB in the review of financial conflicts of interest of research. • Chapter 10 – Qualitative Research: Clarify the type of observational studies referred to within the context of the • guidance. The observational research addressed in this article is of two kinds: "non-participant" where the researcher observes, but is not a participant in, the activity (also known as "naturalistic observation"); and "participant" where the researcher engages in, and observes, the activity. Participant observation is often identified with ethnographic research, in which the researcher's role is to gain a holistic overview of the studied context through engagement in, and observation of, the setting to describe its social environments, processes and relationships. Participant observation may or may not require permission to observe and participate in activities of the setting studied. In some situations, researchers will identify themselves and seek consent from individuals in that setting; in others, researchers will engage in covert observation and not seek consent. • L. Walker identified that these changes put the onus on the researcher to explain covert research and why consent is not being sought (in situations where there could be some expectation of privacy). • Chapter 11 – Interventional Research (formerly Clinical Trials): 1. Introduce a new, revamped chapter with a new title reflecting the wider scope of the chapter. Includes research beyond clinical trials that involves prospective assignment of participants to one or more interventions, and research that presents more-than-minimal risk to participants, 2. Preserve guidance that specifically applies to clinical trials in a separate section of this chapter. • For the purposes of this Policy, an interventional study is any study that prospectively assigns individuals or groups, to receive, or not receive, one or more interventions and that may involve more than minimal risk to participants. This definition includes pilot	

		studies/trials, all phases of clinical trials and studies that may affect health or other aspects of participant welfare (e.g., educational opportunities, socio-economic status, access to services). An intervention is the planned imposition of a set of conditions on participants for the purposes of research. The conditions may be such things as a task, an activity, a treatment, exposure to stimuli, or a change to environment. The purpose of the research may be to describe, measure, evaluate, explain, or observe participants' reactions or responses to one or more of the imposed conditions. For the purposes of this Policy, a clinical trial is any interventional study in which both the intervention(s) and the outcome(s) are health-related. L. Walker identified that this chapter has been tailored toward social science research as well – the previous version was very focused on the bioscience side. • L. Walker indicated that Chapter 9 has been extended to more than just Indigenous populations - that researchers should engage in community representation wherever appropriate. • L. Walker confirmed that these are simply proposed changes at this point. They are open for people to comment on. If the board would prefer, we can compile the comments from all board members and respond back as an institution.	
4	**Tabled Agenda Items**	**Decide whether our office should be putting clearance notes on the certificate itself for clarity ("partial clearance" with conditions listed on the certificate):** • The current process in the REO was reviewed: if researchers send back their clarification responses and there are only minor concerns that do not warrant a further clarification request, the office will send out the clearance certificate with notes in the body of the email (e.g., please send the school board ethics clearance once obtained). However, it came to our attention that other institutions place these notes on the certificate itself (i.e., clearance will be permitted once these notes or points are addressed). • L. Walker indicated however, that clearance cannot be given conditionally – therefore we should not be indicating this in any way on the certificate. • Board members could see that with compliance cases, it may be helpful to have the notes in a more obvious place such as the certificate (this would give us a clear paper trail). • However, it is possible for these notes to complicate and confuse the process. For example, we often ask researchers in the notes to send in a graduate student's TCPS2 CORE tutorial certificate prior to their engagement in research. This may complicate journal submissions for the researchers if this note were to appear on the clearance certificate; journals may assume full clearance was not obtained. • A board member inquired about whether it would be possible to provide clearance for shorter period – for example, clearance for one month. Within that month, researchers must complete and send in proof that the notes were taken care of (i.e., the conditions are met). Once they have been met, clearance for one year could be provided. • L. Walker noted that researchers are not supposed to begin the research until those notes are addressed. Therefore, clearance for a shorter period would not address this properly.	

		• The REO indicated that in the past, we have split up projects into two certificates (still one file but a clearance certificate is granted for Part 1 and Part 2 separately) if the project is complex. However, this is not generally a standard of ours. • Board members agreed that not having a "clean" letter could be problematic and confuse researchers, journals etc. As of now, the office is providing the notes at their own discretion and board members agreed that if this system has been successful so far, we will continue with this strategy. **Discuss whether a longitudinal study that has the same core questionnaires and modifications to additional materials every year require a new application (or simply submit a modification):** • L. Walker provided some context around this discussion point: we have some researchers at Brock that run the same project across several years. They develop a large database of this core data – then every year, a graduate student is added to the project and they bring an unique component to the study. For example, the PI continues to administer the same set of core questionnaires however, each student adds a new set of measures to the battery, depending on their unique research question. This way, the PI still has access to the data from the core questionnaires for his larger longitudinal study, while the student can glean their data for their thesis project. Every year, a modification is submitted on this project to remove the student and the questionnaires personal to their project from the previous year, and add the new student and the questionnaire personal to their project for the upcoming year. The board in the past was concerned about whether this number of modifications and this strategy for mass data collection was acceptable. • The Chair clarified that based on the description of the project, it appears to be a series of cross sectional studies (i.e., new cohorts of participants every year) versus a longitudinal study. This cleared up several of the board member's concerns, given that re-consent from participants would not be required in a cross sectional design. • The REB created a policy a few years ago that after 5 years or 5 modifications, a researcher is required to resubmit their application (difficult to assess what the project looks like after several years and several changes). • The REO asked board members their thoughts on whether each student in the above example should submit a new application or whether we can continue to allow modifications (i.e., new students added because their thesis is part of the overall work and umbrella purposes of the larger study) and follow the policy regarding resubmission after 5 modifications. • L. Walker indicated that we have both cases come through the office – some PI's require their students to submit their own independent application where others simply submit the modifications. This does not appear to be consistent across disciplines and the REB does not have any guidance or policy around this. In other words, the REB needs to determine whether we open to approving "programs" of research or only approve individual projects. • Board members believe that if the purpose of the study is clearly different, it should be submitted as a new application.	

		• L. Walker indicated however, that the PI's often write the application broadly enough that their student's perspective/project can often fall under the broad description. • L. Walker indicated that in the proposed changes to the TCPS2, they have identified that course-based research will not go through the REB. It will be defined as strictly pedagogical, meant to train students on how to do research. Course-based research should not be designed as a publishing opportunity. It may be required to be reviewed by an individual at the university (e.g., someone in the same department or Faculty) however, this will not fall under the scope of the REB. The problem REB's are encountering right now are professors engaging in course-based research and then asking their student to consent to allow their data to be used for the professor's publishing purposes. • This is an example of one of the topics that could be given to the new policy and guidelines committee (i.e., the Brock requirement regarding whether every thesis exit project is a stand-alone application or whether we will allow modifications to occur). • Board members weighed the increase of workload to the office (if we accept every new student as a new application) with the pedagogical benefits of completing their own application and undergoing the ethics process. • L. Walker indicated that the office is firm about the resubmission after 5-years rule however, has been more flexible with the number of modifications. When we get a file with many modifications, we look at the types of modifications made. For example, if they are all simply personnel changes or changing the time commitment associated with the study after pilot testing etc. (more benign requests) we will allow for more than 5 before we ask for resubmission. The board felt ok with the office continuing to make this discretion. **Discuss processes involved when multiple students utilize the same data set for different research projects and intentions:** • Board members feel that if the consent form is clear that several individuals are collecting data and using it for independent purposes, this can be submitted as one application. All projects in these cases share a similar purpose and their research questions are often very closely linked (otherwise it would not be possible to answer their questions all from the same dataset). Researchers who partake in this strategy have each student write their own individuals research papers/thesis. • The Chair asked for this item to be deferred to the next meeting to ensure all voices, opinions and specialties are accounted for.	
5	**Adjourn**	**Meeting adjourned at 1:45p.m.**	