BROCK UNIVERSITY RESEARCH ETHICS BOARD
Tuesday September 27, 2022
12:00 – 2:00 p.m.
Microsoft Teams

Minutes of the HREB Meeting

Attendance:

Lori Walker (non-voting)
Chae Lynn Bush (non-voting)
Stephen Cheung
Kimberly Gammage
Chris Cochrane
Terrance Wade
Maureen Shantz
Shawn Beaudette
Tim Kenyon
Matthieu Dagenais
Connie Schumacher
Michelle Vine
Kirina Angrish
Manal Alzghoul
Sara Madanat
Taranjot Dhillon

Regrets:

Alyssa Bax (non-voting)
Nicole Chimera
Heather Church

MINUTES			
ITEM		**DISCUSSION**	**ACTION**
1	**Motion to approve Agenda**		Motion to approve: MS Seconded: MV All in favour
	Motion to approve August Minutes		Motion to approve: CS Seconded: MV SB Abstained All else in favour
	Motion to approve August Decision Report		Motion to approve: CS Seconded: MV All in favour
2	**New Business**	• For new members, the decision reports consist of all the decisions that occurred in the previous month (approvals, continuing reports, modifications, and final reports). Some of these decisions may not have crossed your inbox, however, the Office staff and the Chair have reviewed them. • If anyone has any questions, please contact Lori or Chae. Lori has mentioned that the new member training was very successful.	
3	**Discussion Items**	• REB Member Introductions o Stephen is the HREB Chair. o Lori is the Manager of Research Ethics. o Chae is the Health Sciences Research Ethics Officer. o Chris is from Vancouver with a PhD in Experimental Medicine serving as a community member on the REB. o Connie is an Assistant Professor in Nursing serving her second year on the REB. She is also a member of the Aboriginal Research Advisory Circle (ARAC). o Kim is from the Department of Kinesiology who has served on the REB for many years o Kirina is a 3rd year PhD candidate working under the supervision of Dr. Kim Gammage. o Manal is an Associate Professor in the Department of Nursing.	

		○ Maureen is a community member who has served on the board for many years. ○ Michelle is an Assistant Professor in Health Sciences who joined the board earlier this year ○ Sara is a PhD student under the supervision of Dr. Wendy Ward. ○ Matt is a PhD student under the supervision of Dr. Kim Gammage. ○ Shawn Beaudette is an Assistant Professor in the Department of Kinesiology serving his 3rd year on the board ○ Taranjot is a PhD student under the supervision of Dr. Kim Gammage. ○ Terry is an REB member. ○ We have a good mix of students and faculty members with different backgrounds. • Message from Tim Kenyon ○ Here to speak about the trajectory of the research ethics boards and their significance on the aspirations of the university. ○ It's important to recognize that the REBs (at the chair and member level) serve an important role that enable our colleagues to do their work. They should be greatly supported as there's no substitute for an REB. ○ The chairs have done a great job on taking on the role of the REB and ensuring that the board is functioning well. It is not always easy finding a chair, and it is typically an internal process voted on by the board. The REB is making great progress to get there. ○ I would like to highlight the remarkable role of the REB and Office of Research Ethics when the pandemic hit. It was a low probability event, yet we were able to move into a position of readiness because the right policies were already in place. Taking measures such as putting SOPs in advance can help the community during these unlikely circumstances. ○ During the pandemic, some REBs in Ontario only reviewed research related to COVID-19. At Brock, the REB didn't slow down and proceeded to review all research. I want to give recognition to those who were members during that time and welcome new members to a board that is high functioning ○ We are looking at forms of support for ARAC, honoraria for its members, and new terminology for the name. These processes will continue to develop as we as an institution learn more about our relationship with these individuals. ○ There are four main divisions that report to the Office of the Vice President of Research. The Office of Research Ethics (ORE) and the Office of Research Services (ORS) make up two of these divisions. As such, the ORE and ORS are not above or below one another. ○ You are all in important research leadership positions. The REB is crucial for research to occur to Brock, and we as a community need to acknowledge the role it plays. Let me (Tim) know if there is anything that can be done to support the REB further. Dr. Kenyon is at arm's length to the REB, however, he can help with administrative support. ○ Contact Dr. Kenyon directly or Stephen can bring any requests as a board to Dr. Kenyon. • Terms of Reference ○ Much of the office processes haven't officially been transferred to paper. This is the first time in the last two years that we have been fully staffed in the office, so we would like to take advantage of that. ○ We have Standard Operating Procedures (SOPs) for the office that haven't been reviewed since 2017. We used to have a sub-committee of the board that handled this work. However, we don't want to get in the habit of cancelling board meetings if there isn't a full board review. Part of our role is to develop and contribute to best practices at the university. ○ Moving forward, we will attach an SOP to the email that you receive about a week before the meeting. You can review it and come prepared to the meeting with any comments that you have. Together we will work on the document and compile comments. Ideally, we can vote on the decision in the following meeting.

		○ First will be the terms of reference for all members of the board. Building the criteria for who is a voting member, the duration of terms, etc. • SOP – Microneurography (Revised from full-board review of 21-322 KLASSEN) ○ We have about 7 standard operating procedures (SOPs) for specific measures used in research at Brock. For example, Stephen's research measures rectal temperature. Stephen used to have to re-explain this procedure in each of his applications which resulted in the same questions being asked. ○ Instead of outlining this procedure every time, the researcher can build an SOP based on standard practices. This can then be approved by the board so that the researcher can reference the SOP in the application and not require a repeated full board review. However, the researchers must declare any deviation from the SOP and consider the risk that arises from that deviation. ○ SOPs make the review process easier for both the researcher and the REB. ○ Not everything is amendable to an SOP. For example, TMS and EEG have not been developed into standardized procedures as there is so much variation between researchers. ○ This Microneurography SOP we are discussing today has been submitted to the REB by Stephen Klassen. Some of you have not seen any of this SOP, but it was initially reviewed in a past full-board meeting. We requested clarification and he submitted the revised version that was sent to you last week. In the coming years, he will be conducting a lot of microneurography studies. ○ Microneurography is a tool to measure Muscle Sympathetic Nervous Activity (MSNA). It involves a fine needle (similar to the width of the human hair) that is inserted into the peroneal nerve around the knee. A number of interventions are then applied so the control of the cardiovascular system can be measured. The SOP covers the methodology, how we can safely prepare the body, inclusion/exclusion criteria, etc. ○ It doesn't need to be a medically controlled act as it is not something that is clinically used. According to the controlled medical act, anything that goes into the body is typically a controlled act. However, the board has decided that there are procedures that are research-based with many clinicians who do not have the relevant experience. There are some things that do require medical, such as a technician for blood draws. However, there are some researchers that have years of experience in this area which then we do not require. ○ Member Question: Question about the objective of the SOP. Does the SOP outline the methodology and potential risk so that it can be referenced by the REB and balanced with the benefits of the research? ○ Chair Answer: The SOP does outline the risk; it is a procedure where the risks of microneurography have been pre-reviewed and approved. However, if there are additional interventions, the researcher and REB must consider whether previous risks have been magnified or changed. ○ Member Question: Are we addressing whether these risks are acceptable or approving the procedure? ○ Lori Answer: An SOP outlines the methods to complete the procedure. It often includes discussion of risk, but it is intended to say this is how something will be done every single time. The board is responsible to look at the rest of the risks that arise from the research and the specific population. Experts in this field have accepted this standard procedure so that the researcher doesn't have to keep writing it over and over again. The procedure has been approved in terms of the steps itself, but it has not been approved in terms of risk or the specific context of the study. ○ Member Question: The needle was mentioned to be autoclaved based on the described procedure. Is this procedure an industry standard/best practice or has it been built itself? ○ Chair Answer: Almost certain that this is a best practice that is frequently used but we can double check with researcher. ○ Member Question: How often are the SOPs reviewed?

		○ Chair Answer: This will be one of the processes that will be developed as we work through the terms of reference. One SOP isn't meant to be for a specific researcher, anyone at Brock can use it. As an office, we should keep track of who initiated the SOP and develop rules about when these should be re-reviewed. ○ Member Question: How and where would a researcher contact and express their concerns about an existing SOP? ○ Chair Answer: Contact the Office of Research Ethics. ○ Member Question: Do participants have a right to refuse a microneurography needle that has been previously used in a previous participant? ○ Chair Answer: We should ask that this be made explicitly clear that the participant can request a new needle to be used. ○ All existing SOPs should have a date that it was reviewed and a date where it should be re-reviewed. This is something that we need to install. ○ In terms of disinfecting, we can look at the manufacturer to ensure that their recommendations were being met. Once it is finished, we can send the entire document with highlights to Layla at Brock (Health and Safety) to ensure that the needles are being disinfected properly. The office also checks with other standards in other institutions. It is good that we aren't making all of the decisions internally. ○ The other close by university in Ontario that is a leader in microneurography is Western. Kevin Shoemaker trained Stephen Klassen in his procedures. If we need follow up or comparison, it is recommended to check in with Western. ○ Member Question: Will we reach out to other universities ourselves or do we ask the researcher to reach out and provide that information from other universities? ○ Lori Answer: We do both. For example, with Stephen's research, we asked him to provide experts to contact. We can also find them ourselves to request an external review and provide their opinion. ○ When we don't have the expertise within the board, we do have the ability to ask beyond. For example, we made a call out in the past for researchers who were based in a specific culture to review the application. We don't have a physician on the board, but we can seek medical advice. If there is any doubt when you are reviewing, please raise that doubt to find someone who can bring in external assistance. We are never forced to make decisions ourselves, even if it requires payment. ○ Quorum isn't just how many people vote, but it is also who is voting. For example, if 4 people vote yes and the expert votes no, we don't pass it. ○ Member Question: Question about the process. Do you invite a member of the research team to come answer the questions for an SOP? ○ Chair answer: Stephen submitted an application and SOP for microneurography at the same time, so he was able to respond to clarifications in our full-board review. However, these processes are distinct as the SOP can be used by anyone. Even though Stephen Klassen is the one who initiated it, we shouldn't think of it as his SOP. ○ We will request clarification and revision from Stephen Klassen about the concerns that Maureen has raised. After it is cleaned up, we can hopefully vote in October on its approval. • Revisit Clinical Trials Ontario (CTO) non-clinical pilot project ○ SOPs are the administrative processes that determine which files go straight to the chair, which files are delegated to the office, etc. ○ Thirty-two administrative SOPs were reviewed through CAREB and its American equivalent. We have accepted these SOPs for use, however, we have not converted them into Brock formatting. As these are clinical SOPs, there were questions about non-clinical institutions, such as Brock. ○ Clinical Trials Ontario has developed non-clinical SOPs and hopes to review the process of institutions for non-clinical projects. We have signed up for this pilot project. In the new year, they will be coming to Brock to look at our reviews. We can then say we have had a quality review of our processes and we passed.

		○ There could be board member and chair interviews to inquire about our procedures and processes. However, the pilot will mostly take place on the administrative side. ○ There is no body that has been funded to enforce REB processes, and the TCPS would be in conflict of interest if they reviewed their own processes. ○ No specific details will be required from any file. For example, they will be looking at how new files are triaged in non-clinical settings. However, there are things that are different in clinical settings. We want to make sure that we are meeting the requirements for non-clinical settings. If clinical, the file would be sent straight to the chair whereas non-clinical research is triaged by the research ethics officer. If you have any comments about things that are working and/or aren't working, please let the office know. • Revisit REB Member Survey ○ This is also a project intended to improve our best practices and survey our members to get more information on their background, their experience on the board, etc. Last board meeting, we presented this idea and invited anyone with survey research to help and meet with the office to develop the survey. ○ We have already picked out some questions and communicated with other universities about their surveys. We have gained access to Qualtrics and will be using that platform. ○ We will go back to past members and include new members. We welcome any criticism to the REB as well as recommendations for onboarding practices, training, or support services. We will also ask questions such as whether you have read the TCPS, whether you think it is necessary, whether the turnaround time is reasonable, etc. We haven't done this since 2015 so it's time to survey the board's opinion. ○ Chair Question: How close are we to rolling it out? ○ Lori Answer: I would like to see it go out in the beginning of December and be due in January. This is because I would like to incorporate questions and suggestions about the new system. ○ Chair Response: I would prefer to keep the online system separate from the member survey about REB processes and member training. The online system questions may dominate the survey. ○ Lori Response: We will aim for end of October but will want all responses by the beginning of December. Communicate results in January. • Other Business ○ The board has decided to upgrade our online TCPS 2 certifications to the new 2022 version. The soft deadline for this was September and the hard deadline is December 31, 2022. ○ Chair Comment: I met with Lori, Chae, and Alyssa to go through the new Synto system. We went through a clinical application (the longest one). In my experience of online systems, the new system is clearer, and the questions are less ambiguous. For anyone with experience submitting files to Brock, the new system isn't very different. The questions are logically laid out. It will save a lot of time for the office and make the lives of board members easier. ○ End of October is the expected soft launch of the system. Stephen will likely be the first to submit an application. We as a board will work together on the first 1 or 2 files to review them for training on how to review on the new system. ○ January 1 is the hard launch for all new files. We're still working on amendments and annual renewals. Researchers will be staggered into the system. Meetings will eventually be scheduled in the portal so that we can move away from emailing. ○ If any researchers are looking to submit applications and want to be apart of the pilot for the new system, please let the office know. ○ Starting October 12th, we have Wednesday afternoons scheduled for in-person training sessions and meetings. If you are interested in meeting and coming for training, let us know which Wednesday you will be coming. ○ Chae will send everyone information about this meeting room, as well as the link to the new TCPS training.

4	**Adjourn**	**Meeting adjourned at 1:43 p.m.**	Motion to Approve: MV Seconded: CC All in favour