BROCK UNIVERSITY RESEARCH ETHICS BOARD
Friday, January 15, 2021
12:00 – 2:00 p.m.
Teams

Minutes of the HREB Meeting

Attendance
Shawn Beaudette
Stephen Cheung
Nicole Chimera
Gail Frost
Kimberley Gammage
Carly MaGee (non-voting)
Megan Magier
Jennifer Matunin-Brown
Maureen Shantz
Craig Tokuno
Terrance Wade
Lori Walker (non-voting)
Danielle Williams
Jenalyn Yumol

Regrets
Jean Armitage
Robert Kumar

MINUTES			
ITEM		**DISCUSSION**	**ACTION**
1	**Motion to approve Agenda** • Approved **Motion to approve November, December Decision Reports & November Minutes** • Approved		Motion to approve: TW Seconded: NC All in favour Motion to approve: GF Seconded: MM All in favour
2	**Update**	**Update on Lockdown Procedures in Ethics** • LW provided an update on how ethics is functioning during the current lockdown. • All in-person research that previously received authorization was shut down on December 23, 2020. The Principal Investigators on these projects were informed by the Associate Vice-President Research via email. • In-person research can still take place in Stage 1 (lockdown) if takes place only with people in the same household. • We are no longer offering the “preview” option given the authorization process has changed slightly. Now all documents (Health & Safety, Ethics etc.) need to be submitted at the same time. This should clear up some confusion for researchers as well if everything is submitted together. • LW is getting a lot of questions asking what will happen when the lockdown is lifted. Can researchers who previously had authorization just start up their research right away? As far as we know in the office, researchers will need to go through the authorization process again given the stage/restrictions may change from the first authorization.	

3	**Education Item**	**Presentation on Clinical Trials** • The Chair explained that he created this presentation for the HREB for two reasons: to ensure REB members have the knowledge needed to flag files as potential clinical trials when they come in for review; and to help confirm definitions and terminology for the clinical trials guideline we intend to create for our researchers. • The Chair clarified that clinical trial registries need to be updated throughout the course of the project (starting the recruitment phase, analysis data etc.) including reporting results and conclusions. This might be new information to some. • After board members heard the TCPS2 definition of a clinical trial and some examples from other universities, members encouraged the office to adopt a very tempered definition for our guideline. With the TCPS2 definition, a lot of what researchers do in the Faculty of Applied Health Sciences could be considered a clinical trial. Once our guideline is created, education for researchers and the board establishing our expectations would be helpful. • Members also suggested allowing researchers the opportunity to justify to the REB if they do not believe their project falls under the definition of a clinical trial. For example, if you are measuring blood pressure as a secondary outcome. Although this could be considered a “health outcome,” it is not the main purpose of the study. • Members who have experience registering a clinical trial reiterated that it is not a trivial process; it can be time consuming and tedious. We need to carefully consider our definitions. • A member suggested looking at the definition of a health outcome from a public health perspective. This may already be well defined and helpful for our purposes. • Another member gave the example of funding bodies as a loose parameter for measuring what projects are looking at “health outcomes.” For example, NSERC and SSHRC do not fund any projects examining health related outcomes. So, if a body image intervention is funded through SSHRC, by definition by the Tri Council agencies, those body image outcomes would not be considered health outcomes. • A few other examples were presented including from the National Institutes of Health. • A member brought up the idea of whether acute and transient outcomes would be considered a clinical trial (immediate changes as a result of the research). For example, temperature changes may go up while the study is taking place but come down immediately after. Given these are transient outcomes, this might not meet the definition of a health outcome. But if the researcher was examining if there was a drop in a participant’s blood pressure after 6-weeks of heat training, this is a much more clinically relevant outcome.	

		• LAW talked briefly about cases where the study itself is not a clinical trial, but the researchers are proposing the use of a product off label. We might want to write something about these in our guideline, so researchers are not surprised that they need to go to Health Canada for approval (even if their study is not a clinical trial). • For example, a previous study we reviewed proposed the use of vitamin D for periodontal health. Health Canada required this to be reviewed by their board given they said vitamin D's on label use is for strengthening bones and teeth, not gums. So, the study was proposing the use of vitamin D off label. • Five examples of previous studies that have come to the REB for review were provided and board members voted on whether they thought it constituted a clinical trial based on the information provided thus far in the presentation. This exercise sparked helpful discussion among board members which will be summarized here. • Members discussed whether neural, brain excitability, muscle activation outcomes count as health outcomes. The Chair indicated that clinicaltrials.gov lists these as primary outcome measures; in other words, there are studies registered as clinical trials that examine neural, brain excitability, muscle activation. This means the researchers or REB at their institution would have considered these to be health outcomes. The Chair explained that a lot of these trials involve certain patient populations: older adults, people who have experienced a stroke, people with known balance deficits etc. Does that make it more of a clinical trial? NIH says no. Clinical trials can involve healthy adults as well; something else for us to consider for our guideline. • Members talked about the specific purpose of the study and how isolating those outcomes may help us determine if it is considered "health" related. For example, a study examining balance stability versus risk of falls. Balance stability is a more mechanistic outcome so may not be considered a health outcome, but risk of falls may lean closer to health. Perhaps we need to closely consider the dependent variable. • Members discussed the next example about whether "help seeking intentions" or "mental healthy literacy" would be considered a health outcome. Although being more literate in mental health may make an individual more likely to receive help thus leading to better mental health, this is a far-reaching impact of the study and not the primary outcome. Members agreed that these measures might not be direct enough. For example, a participant could improve their mental health literacy but not improve their mental health. However, if the study was examining depression or anxiety directly and researchers wanted to track improvement, members agreed these would constitute a health outcome. • The next example brought up the importance of examining the purpose of the study. Although it may	

		look like a clinical trial on the surface (e.g., experimental and control group where an intervention is used to determine how verbal cues impact physique anxiety in novice weight trainers), the underlying purpose of the study needs to meet the definition of a clinical trial (to determine what verbal cues personal trainers should be providing would not be considered a clinical trial). If the purpose is to help trainers help their clients, the outcome is not “health” related. This makes it interesting because how a researcher words the purpose changes whether their project falls under the clinical trial category or not. • Members agreed our definition needs to place emphasis on the use of a direct health outcome. Although a study may measure health outcomes as secondary measures, we should only consider it a clinical trial if it is measuring a health outcome **directly**. • The board had a discussion about whether measures need to be clinical or diagnostic to be considered a health outcome, specifically regarding mental health outcomes. For example, “mood states” are very different from “anxiety.” We need to be aware of this when making our guideline.	
4	**Adjourn**	**Meeting adjourned at 1:51 p.m.**	Motion to adjourn: MS Seconded: SC All in favour