

**BROCK UNIVERSITY RESEARCH ETHICS BOARD**  
**Thursday, May 4, 2017**  
**12:00 – 2:00 p.m.**  
**MC D350-L**

**Minutes of the BREB Meeting**

**Attendance**

Jean Armitage  
 Stephen Cheung  
 Kimberley Gammage  
 Lara Green  
 Matthew Mallette

Jennifer Maturin-Brown  
 Greg McGarr  
 Sandra Peters  
 Ayda Tekok-Kilic

**Regrets**

Kirsten Bott  
 Gail Frost  
 Jason Liu  
 Craig Tokuno

<b>MINUTES</b>		
<b>ITEM</b>	<b>DISCUSSION</b>	<b>ACTION</b>
1	<p><b>Motion to approve Agenda</b></p> <ul style="list-style-type: none"> <li>• Approved</li> </ul> <p><b>Motion to approve April Decision Reports</b></p> <ul style="list-style-type: none"> <li>• Approved</li> </ul> <p><b>Motion to approve April Minutes</b></p> <ul style="list-style-type: none"> <li>• Approved</li> </ul>	<p>Motion to approve: LG            Seconded: JA            All in favour</p> <p>Motion to approve: KG            Seconded: JA            All in favour</p> <p>Motion to approve: JMB            Seconded: MM            All in favour</p>
2	<p><b>New Business</b></p> <p><b>The REB Sub-Committee on Guidelines, Practice, and Procedure (GPP)</b></p> <ul style="list-style-type: none"> <li>• The four new documents to be approved by BREB today were reviewed:</li> </ul> <p>1) REB Guideline – Meetings, Quorum, and Attendance</p> <ul style="list-style-type: none"> <li>• The office informed members of the comments/suggestions made by SREB to this document.</li> <li>• Members inquired about whether we have latitude to change our quorum requirements for business items. Is there a mandate for business decisions outlined in the TCPS2?</li> <li>• It was clarified that the TCPS2 does not dictate how decisions should be made (e.g., in-person versus electronic vote), just that consensus is ideal.</li> <li>• There have been cases where comments from the community member were accepted via email however, it was agreed that this method is not ideal for full board meetings (there is too much information, body language etc. lost in decision making when meetings are held via Skype). The in-person discussion changes the decision-making process – the board agreed that in-person attendance and quorum is necessary for these meetings.</li> <li>• The board discussed how policy/educative meetings</li> </ul>	

		<p>may differ. For example, when developing the venipuncture guidelines, a great deal of discussion occurred at the meeting that informed the development of the document. This would have been very difficult to achieve over email.</p> <ul style="list-style-type: none"> <li>• Members wondered about topics that do not require a discussion - could these operate on a proxy vote?</li> <li>• Board members felt that anytime that a REB decision is made, the meeting should have quorum in-person.</li> <li>• Members felt that in-person quorum would not be necessary for meetings that are educative with no decisions made.</li> <li>• Members pointed out however, that even at educative meetings where there are no full board files, most times the board is still responsible for approving the agenda, decision reports and minutes from the previous month's meeting. REB members still have oversight over these documents. Without quorum, it could be argued that these documents were not ratified.</li> <li>• In cases where the meeting does not have quorum however, documents still need to be approved, it would be considered on a case-by-case basis whether an ad-hoc meeting was necessary.</li> <li>• Members inquired about whether there is a standard for how many REB meetings a member must attend per year. The office confirmed that members are required to attend 10 meetings a year.</li> <li>• It was discussed whether this requirement should be incorporated into the training of new members so they can understand what is expected of them and ensure full attendance at these meetings (to avoid constantly scheduling ad-hoc meetings to make decisions).</li> <li>• This document will go back to the sub-committee to incorporate the BREB's preference: that any meeting where decisions will take place, quorum is required.</li> </ul> <p>2) REB Standard – Faculty Supervisors and Student Researcher</p> <ul style="list-style-type: none"> <li>• The office informed members of the comments/suggestions made by SREB to this document, and BREB members agreed.</li> <li>• Members discussed the concern about adjunct faculty and sessional instructors – however, it was identified that these concerns will be incorporated into a different guideline document, regarding who can be a Principal Investigator (PI).</li> <li>• In terms of adjunct faculty, they do not necessarily need any academic appointment somewhere else, meaning in some cases, they are independent scientists. Right now, we still require both adjuncts and sessional instructors to have a full-time faculty member at Brock represent their project as the PI. The reason being that if they finish their contract before they finish the research, they would have no affiliation with Brock.</li> <li>• However, this is not necessarily fair to that faculty member because they are simply rubber stamping the</li> </ul>	
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		<p>application and in most cases, are not involved in the project at all (yet they technically have overall responsibility and oversight over the project).</p> <ul style="list-style-type: none"> <li>• In this new guideline (who can be a PI), we also need to establish rules around whether people external to Brock can apply on their own or whether they require an internal, Brock faculty member to oversee Brock's involvement. For example, would we allow an independent, external research to apply as the PI, use our participants but not our resources or collaboration?</li> <li>• The office also highlighted that some sessional instructors, even if research is not part of their contract, are interested in doing course-based research in their teaching. For this we generally allow them to act as the PI since the research would end when the course is over (i.e., they would only be doing research when they had an affiliation with Brock).</li> <li>• These points will be considered when the sub-committee develops this guideline.</li> <li>• Members discussed a point on the current guideline regarding faculty supervisors: students must complete their research proposal prior to applying to the REB. Members indicated that the definition of a proposal is very different across departments. In some departments, the proposal is simply a planning meeting with the student and committee members. In others, it is a very in-depth defence including a presentation and question and answer period with the committee.</li> <li>• The REB's concern is that, particularly for full board reviews, we are under the assumption that the committee, possessing relevant expertise in the area, has already weighed in on the project and made any suggestions/edits they felt were necessary. In cases where student projects seek REB approval before their proposal, we often see modifications submitted after the proposal to incorporate changes made by the committee. This is very resource intensive for the office and the board.</li> <li>• To avoid this, other institutions have a question on their ethics application to confirm whether the research has been approved by the supervisory committee.</li> <li>• REB members reiterated that the proposal is defined as something different for each department.</li> <li>• The office clarified that the definition of a proposal should be outlined in each program's procedures and the graduate student handbook. It was noted that this requirement for the supervisory committee to approve graduate student research prior to applying to the REB has been in place at least since 2003 by Senate, and is outlined in the Faculty Handbook.</li> <li>• The board talked about the possibility of students coming into an existing project - if there is a project ongoing and a student starts working on a piece of that larger project for their thesis/MRP, should they submit an independent REB application?</li> </ul>	
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- The board agreed that these changes should be submitted as a modification, and not new applications (unless data is being analyzed for a different purpose outside of the original application).
- If a PI builds this design into their project ahead of time (and informs the REB in their application), we would simply need to be informed of the changing personnel on the annual renewal report, and a formal modification request would not be needed.
- It was agreed to take this standard back to the sub-committee to incorporate changes about the differing proposal definitions across faculties, departments and disciplines.

### 3) SOP 01 Saliva

- The Chair explained that this SOP was vetted by two different researchers who use different methods of collecting saliva. It has also been reviewed by Leila in Biosafety and now requires the BREB's approval.
- A member wondered if the SOP should tell participants the reason why saliva is being collected. The Chair clarified that this information would be present in the consent form. The SOP is specifically for the researchers to ease their writing of the protocol (e.g., "saliva will be collected according to SOP 01 with the following changes..."). This allows the REB to be sure that the researchers are following the guidelines we outlined in the SOP.
- A member of the board who has collected saliva samples in the past felt the document was written clearly.
- A member asked whether the samples need to be collected in a controlled/sterile setting. The board clarified they do not. Some protocols actually ask participants to take samples at home. This does not pose any risk to the participants. Leila is reviewing all the SOPs from a biosafety point of view, so she would have considered these details. The REB's concern is the participant, with some points regarding researcher safety.
- This SOP will be used by the sleep lab, with credit given to the BREB.
- A member suggested that we add a point to the SOP, reminding the researchers that they need to complete the Request for Human Tissue Samples application and obtain a Biosafety permit. The Chair agreed to add this point to the current SOP, and to the SOPs regarding blood and urine collection as well.
- A motion was put forward by GM to approve SOP 01 with those minor revisions. Seconded by ATK. All members voted in favour.

### 4) SOP 03 Venipuncture

- The Chair explained that this SOP has now gone through several experienced researchers (Anthony

		<p>Bogaert, Andrea Josse, and two students who are familiar with the protocol) and Leila for review. Andrea Josse in particular is a trained phlebotomist and has done considerable hours of training. The comments from these reviewers were incorporated into the version presented to the BREB. There was one change suggested by a researcher that had impact on biosafety and therefore, once the BREB approves the document, it will go back to Leila for her final approval.</p> <ul style="list-style-type: none"> <li>• In order to streamline the information in both the SOP and the venipuncture guidelines, the following point under purpose/background was included: “According to the Brock REB Guidelines on Blood Draws, all phlebotomy or venipuncture in research studies at Brock will normally be done by a certified and current laboratory technician (e.g., Life Labs) or a registered nurse. As technicians typically have their own detailed procedures according to their training, this document is meant to outline the minimum standard.” This was included to accommodate the fact that the guideline is contextualized and we were previously criticized for implementing it as a policy.</li> <li>• The Chair agreed to add in a point reminding the researchers that they need to complete the Request for Human Tissue Samples application and obtain a Biosafety permit.</li> <li>• A board member suggested the following edit: “...all phlebotomy or venipuncture in research studies at Brock will normally be done by a certified and current laboratory technician (e.g., Life Labs) or a registered nurse.” This better indicates that the current and certified prerequisite applies to both a technician and a registered nurse. As it is currently written, it would seem a registered nurse could take blood without being certified or current in their qualifications.</li> <li>• Board members suggested there be some details about the veins that can be used (in accordance with this SOP). For example, the back of the hand at the discretion of the phlebotomist.</li> <li>• Members asked whether the back of the hand would require a different needle. It was clarified that the same needle could be used as when blood is taken from the veins in the antecubital fossa.</li> <li>• The board agreed to include the dorsal vein (back of hand) as a possible site for blood draw – at the discretion of the phlebotomist and the consent of the participant.</li> <li>• Some board members worried that “the discretion of the phlebotomist” might give them permission to take blood from other sites, outside of the arm or hand. Members clarified though that this SOP is specifically for arm venipuncture. So, even if we add this statement (at the discretion of the phlebotomist), it just means different veins on the arm specifically.</li> <li>• It was pointed out that this SOP does not address how</li> </ul>	
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many blood draws can be taken over the entire duration of the study. It indicates that a maximum of 2 attempts per participant per sample can be taken with written consent/initials for the second attempt however, there is nothing precluding how many samples the researchers take over the course of the research. The Chair clarified that this information would be in the REB application and the consent form to participants for their information. We would examine this number individually for each unique project.

- As well, in order to maintain quality control, the sub-committee is developing a chart where researchers would have to document:
  - a. Participant ID#, experimental condition, date
  - b. Name of phlebotomist
  - c. Appearance of venipuncture site.
  - d. Participant's tolerance of procedure and particulars
  - e. Number of attempts made (to a maximum of 2 attempts per participant per sample) and written consent/initials for a second attempt (see section B4 below).
  - f. Any complications or difficulties encountered.
- This will identify if there is something problematic with a certain phlebotomist (i.e., if they are constantly going in for a second attempt). Right now, there are no records kept on this.
- A board member asked whether we want to be explicit on the SOP in excluding indwelling catheters. The board agreed to add in a statement under purpose and background indicating that the SOP does not cover the use of indwelling catheters for blood samples. Researchers are still permitted to use indwelling catheters – their procedures simply would not be covered under this SOP.
- The Chair indicated that specific names were also removed from the document to avoid re-editing for any changes in staffing.
- A motion was put forward by KG to approve SOP 03 with those minor revisions. Seconded by MM. All members voted in favour.
- The Chair indicated that the SOPs for VO<sub>2</sub>max and nerve stimulation are currently being developed and will come to the BREB for approval soon.
- The Chair is also working on a sleep lab SOP (specific to their lab).

#### **Office Update**

- The office encouraged any board members who are interested in fulfilling the Chair role starting in December 2017 to contact the office. This would allow the current Chair to mentor this individual until her term is over.
- Nominations for Chair from outside the board were also welcomed.

3	<b>Adjourn</b>	<b>Meeting adjourned at 1:20 p.m.</b>	Motion to adjourn: MM Seconded: LG All in favour
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