BROCK UNIVERSITY RESEARCH ETHICS BOARD
Wednesday, April 4, 2018
12:00 – 2:00 p.m.
MC D350-L

Minutes of the SREB Meeting

Attendance		**Regrets**
Michael Ashton	Carly MaGee (non-voting)	Robyn Bourgeois
Lynn Dempsey	Linda Morrice	Catherine Nash
Ann-Marie DiBiase	Miya Narushima	Mary-Beth Raddon
James Foley	Robert Steinbauer	
Christina Garchinski	Christine Tardif-Williams	
Karen Julien	Kendra Thomson	
	Lori Walker (non-voting)	

MINUTES			
ITEM		**DISCUSSION**	**ACTION**
1	**Motion to approve Agenda** • Approved **Motion to approve January, February & March Decision Reports** • Approved **Motion to approve January & March Minutes** • Approved		Motion to approve: KJ Seconded: LM All in favour Motion to approve: KT Seconded: LD All in favour Motion to approve: CTW Seconded: CG All in favour
2	**New Business**	**Full board review (in camera)** **<u>Presentation on Deception</u>** • LW provided a presentation to the Board on deception. She indicated that the REB's role is to facilitate research and ensure it is as robust as it can be. To do this, sometimes we go back on our principles such as fully informed consent, which may seem unethical. But the TCPS2 allows for this in some cases, understanding that it might be necessary in order to facilitate important research where the benefits outweigh the risks of deception. • TCPS2 defines deception as: "Researchers give participants false information about themselves, events, social conditions and/or the purpose of the research." • This is different from partial disclosure which is defined: "participants may be asked to perform a task and informed about only one of several elements the researchers are observing." • LW put the above definitions in the context of the full board file the Board just reviewed. The researcher on this file is defining psychopathy to participants as	Motion to move in camera: AMD Seconded: CG All in favour Motion to move out of camera: AMD Seconded: CG All in favour

		"personality traits, characteristics, and attitudes" without using the actual word, "psychopathy." The connotations that go along with the word psychopathy are often negative and the construct is falsely understood by participants (thought to be a bad thing when in fact, everyone scores somewhere on the continuum). Having some of these traits is not necessarily bad and can actually be positive in some jobs such as politics, those in business etc. So, although the researcher is not using the actual word "psychopathy," she is not deceiving participants since she has listed all the constructs that make up this term (personality traits, characteristics, and attitudes). • Article 3.1 was discussed: "If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials." However, it does not say that participants have the *right* to withdraw their data. • Article 3.2 was discussed: "Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project." • This means that the information initially provided to a participant in a study involving deception is not informed consent (there is no "re-" consent as there was no original informed consent). As a Board we should not be using language such as "re-consent" given that the first form was not informed consent. • Article 3.3 was discussed: "Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research." This also relates to Article 3.4: "Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research." So, if there is information that could change a participant's mind about whether they want to participate, this needs to be given to participants and they have the opportunity to withdraw consent through the ongoing process. • Article 3.5: "Research shall begin only after the participants, or their authorized third parties, have provided their consent. This is the clearest demonstration that their participation is based on consideration of the risks and potential benefits of the research project, and other ethical principles of the TCPS2. Allowances are made for preliminary conversations which may engage prospective participants around design, terms etc., as these conversations are not themselves, research." • All of the information in Article 3.5 would leave you to believe researchers cannot use deception however, the TCPS2 then goes on to list exceptions to full disclosure consent: "Articles 3.1 to 3.5 set out the default requirements for seeking the consent of individuals to	

		participate in research. However, there are some research questions that cannot be answered without an alteration to these consent requirements. To qualify for exception to the general requirement of full disclosure for consent, the research must meet all of the requirements of Article 3.7A."
		• REBs can agree to make allowances in a situation where the researcher provides justification that they cannot answer the research questions without these alterations.
		• Article 3.7A: "The REB may approve research that involves an alteration to the requirements for consent set out in Articles 3.1 to 3.5 if the REB is satisfied, and documents, that all of the following apply:
		  ○ the research involves no more than minimal risk to the participants;
		  ○ the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
		  ○ it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
		  ○ the precise nature and extent of any proposed alteration is defined; and
		  ○ the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B."
		• In the case of the project reviewed at the full board today, the researcher is not actually using deception. If she was using deception, a waiver requesting alteration to requirements for consent should not be given, since the research is greater than minimal risk.
		• Article 3.7B: "Debriefing must be a part of all research involving an alteration to consent requirements (see Article 3.7A) whenever it is possible, practicable and appropriate. Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate (see Article 3.1)."
		• The TCPS2 includes the language, "whenever it is possible, practicable and appropriate" to allow for exceptions (since a debrief is not required in all cases).
		• The debrief should be a simple, straight-forward, candid disclosure while it is still possible to give participants the option of withdrawing their data (e.g. prior to merging or de-identification), it should explain why deception was deemed to be necessary and should be sensitive to participants needs, feelings, reactions and concerns. The TCPS2 used to say that the debrief should include an apology but that was taken out.
		• The REB should be assessing the risks and benefits of the debriefing itself and whether the plan is appropriate.	

		• Special considerations should be made for those in vulnerable circumstances; those who lack the capacity to make a consent decision. • Researchers must provide a plan to disseminate information about the study to participants and/or their communities (e.g., through local media, direct mail). This plan is of particular importance when the findings may affect participant welfare. • In other words, the REB should consider whether the risk is in the debrief itself. If a debrief is not provided, there is the possibility that a participant may see the study in a journal and realize the purpose explained to them at the time was not consistent with the publication – but this possibility is very remote. • Our Board also takes the stand that researchers can deceive children but not their parents. And we would not ask that the researcher debrief the child and tell them that they were lied to. But we would ask that the parents be informed and decide at the beginning if they agree to their child being deceived. The REB should be considering that a debrief with the child could be riskier than no debrief at all (e.g., could lose trust in doctors, researchers etc.). • Although the file we reviewed today did not use deception, we have said using the word psychopathy is riskier than not (which is why REB members will see it left out of all the participant materials). • In cases like this, where there is the possibility of harming one, we must make sure there is good for the whole. We should be asking researchers about their plans to disseminate results to ensure it is done widly for the greater good (thus justifying this risk). • The three I's of data removal were discussed. • The researcher must give participants the option of removing their data and/or human biological materials unless this option is impossible, impracticable or inappropriate. Board members were reminded that impracticable means incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. • Often the option for withdrawal of data must come before the submission of responses (so that data can be deleted). But in cases where data has already been submitted, researchers are told they must give participants the option of removing their data unless this option is impossible, impracticable (not just a mere inconvenience - it would be so onerous as to jeopardize the study), or inappropriate. • When a researcher proposing waiving of data removal, the REB should consider: ○ Is withdrawal/removal of data possible or practicable? (Anonymous data). The only case where it would be impossible to remove data would be in the case of an anonymous survey	

		and participants were told in the consent form that they can not withdraw responses once they are finished and have submitted. We should be looking at any methods that do not allow for withdrawal of data to ensure there is justification for being anonymous (e.g., either the results are benign and very low risk or data are so risky that we think they should be anonymous). We can ask researchers: "Why can't you collect participant names in terms of allowing them to withdraw their data if they want to?" Then as the Board, we would have to decide whether their reason is justified. ○ Is there sufficient rationale for using collection methods that do not permit subsequent withdrawal of data? ○ Is the option to withdraw appropriate? Could it skew research results, invalidating the study and denying potential benefits to society? Can the researcher satisfy the REB that withdrawal of data would threaten the validity of their research? Invalidation also shows lack of respect for others who have contributed data. This is the argument researchers usually use in their justification. For example, research in psychology on racism. Often the researchers say they do not want to allow people to withdraw because if participants think their data might reveal a level of racism, they often request withdrawal of their data. This would skew the results. Researchers can come to the REB and request a waiver for this. We would suggest that they de-identify data before giving the option of withdrawal. However, even if data are still identifiable at the time that withdrawal is given as an option, we are asked to decide if the benefit to the greater good outweighs the risk to one person. • Where withdrawal of data is not an option: ○ In the absence of informed consent, the identity of the participants shall be protected at all times during and following completion of the project. The REB should be asking specifically about the protections researchers are putting in place for this. Particularly in cases where a participant would want to withdraw their data but cannot. ○ Participants who express concern about the conduct of the project at the time of debriefing, or who contest the limits imposed on withdrawing their data, should be given the contact information for the REB that approved the research. ○ Researchers must report to the REB concerns about the conduct of the project raised by participants at the time of debriefing.	

		• The REB should also consider how debriefing a participant and revealing the true purpose of the study, but then telling them that they cannot withdraw their data, would be disrespectful. In that case, we can say there should be no debrief at all. In fact, the debrief could be more insulting or risky than no debrief at all. • If any participants contact the researchers with concerns about the conduct of project, we would look at the study again to ensure the decision to not allow withdrawal of data is still justified. If there are any changes that need to be made to the procedures to protect future participants or to smooth over the relationship with the concerned participant, the REB would advise on that as well. • LW identified that there seems to be a lack of understanding from researchers that they can argue that withdrawing data could skew research results, invalidating the study and denying potential benefits to society, even if the data are not anonymous. • A member asked, how long would the researcher have to grant a participant the ability to remove the data if they are not anonymous? This is something the Board would have to decide. How long would the researchers need the identifiers? Even if there are still identifiers attached, researchers would not be required to withdraw data just because of that (granted they gave sufficient justification that was supported by the REB). • In a longitudinal study for example, researchers could say that participants have 30 days after completion of the study to remove their data. Even though data would still be identifiable after the 30 days, the argument would have to come to the REB that if a participant could withdraw their data at any time it would invalidate the study and would be disrespectful to those who did give their data for all those years. • The REB should be protecting participants while facilitating research (if researchers can provide justification). • A timeline for destruction of data was discussed – if the student moves to another institution, who owns the data? • LW explained that researchers think the TCPS2 requires data destruction after 5 years. This is not a TCPS2 requirement. They are actually moving towards keeping data available long-term to share with others, make publicly accessible etc. However, researchers are bound to do whatever is written in the ethics application and the consent form given to participants. • Data should also only be used in the way researchers told participants they will use it. So, with data becoming publicly available, researchers are starting to incorporate secondary use of data consent options into their projects ahead of time.	

		• There should be general parameters though around this potential future use (cannot be just a general blanket statement). • Reviewers should decide whether the parameters given around secondary use are descriptive enough and if there is still protection for participants in future studies. In some cases, it may be more appropriate to build in something for re-consent (e.g., "if I want to use this data for future studies, can I contact you later?"). • We should also be looking at the researcher's plan for how data will be secured and stored for these future uses. Will it be kept de-identified? Where and how will it be stored? There should be a clear plan for how the data are going to be managed during the indefinite period. • Researchers can also come back to the Board and request secondary use of data down the road if data are already collected. But we would ask all these questions at that time, which makes it easier get consent for upfront. • LW indicated that Michelle McGinn will be asked to talk to the Board about Scholarship of Teaching and Learning. This is a fine line at the REB level because faculty have the right to teach their courses however they want to and can try different teaching methods as they please. If they happen to find that a different teaching method is more successful, and they want to research and publish about this, it becomes a REB question. We have had researchers in the past teach two sections of the same course differently and analyze course grades to see if they are significantly different. We must consider the protection of students (who are the participants in this case) given they would be used as guinea pigs. For example, if one section has significantly lower grades, what are you going to do? A professor has the right to do this anyway (as part of Scholarship of Teaching and Learning), but we need to ask these questions when it is proposed for *research* purposes. Professors in the past have said they would bell curve grades if there were significant differences. **<u>Ideas for an Education Strategy</u>** • LW explained that we are hoping to develop an education strategy for both the Brock community and beyond. She asked Board members about things they might find useful. Are the education pieces at meetings useful? Should we have meetings that are protected from full board reviews, so we have time to do more education? What information is useful for faculty? In the past, the office has had things like a newsletter, an ethics channel (drupel website) with ethics tips etc. • Members felt that the Q & As are helpful. More sessions like this would be great. LW indicated that the office used to have clinics every other week where we would move around the departments on campus and provide	

		helpful advice. This is something we could consider starting up again. • Members felt that seeing the clarification and revision requests that go out on each file are very helpful in their training. • It was proposed that every 20th applications or so, we could review a file together as a Board and discuss it at a full board meeting (like the training files). Members thought this would be very useful. • Board members agreed the training files (as a group) were very helpful. • LW encouraged members to ask their departments and peers what they would like to see from us in terms of education. • Webinars were suggested. We could make the education presentations available on the website perhaps. • Maybe even having a liaison system where there is one person in each department (e.g., graduate student representative on the board or a graduate student representative in each department) who could come to the REB meeting, discuss larger education issues with the rest of the Board and report the information back to their department. • It was suggested that we should feed any big changes in our process, the TCPS2, guidelines etc. through the Graduate Program Directors in each department (which could be trickled down into all faculty and students from there).	
3	**Adjourn**	**Meeting adjourned at 1:38 p.m.**	Motion to adjourn: CTW Seconded: JF All in favour