

**December 6, 2011**

**12:00 – 2:00 p.m.**

**MCD350-L**

**BROCK UNIVERSITY BIOSCIENCE RESEARCH ETHICS BOARD**

**Minutes of the December, 2011 Meeting**

**Attendees:**

Cratt, Charlene  
Good, Dawn  
Jehu, Deborah (student)  
Liu, Jason  
Marquardt, Drew (student)  
McGinn, Michelle (Vice-Chair)  
Roy, Brian (Chair)  
Stansfield, Melanie  
Walker, Lori  
Williams, Kate

**Regrets:**

Ditor, Dave  
Peters, Sandra  
Shores, Bevin  
Weaver, Tyler (student)

<b>MINUTES</b>		
<b>ITEM</b>	<b>DISCUSSION</b>	<b>ACTION</b>
1	<b>Welcome:</b>  <b>December Agenda</b>  <b>November decision reports</b>  <b>November minutes</b> <ul style="list-style-type: none"><li>· Add Melanie Stansfield to attendance for November meeting</li></ul>	Did not have quorum, all voting deferred to next meeting
2	<b>Updates from Previous Minutes</b>  <b>Full Board Reviews (in-camera)</b>  <b>Guidelines for Online/Internet Research</b> <ul style="list-style-type: none"><li>· LW sent final version to Phillip Wright</li><li>· A decision could not be voted on without quorum</li></ul>	Deferred to next meeting
3	<b>New Business</b>  <b>Update from CAREB Ontario 2011</b> <ul style="list-style-type: none"><li>· Discussed presentation on clinical trials for non-medical universities</li><li>· The definition of a clinical trial was discussed</li><li>· LW was approached by a member of the Panel on Research Ethics (PRE) (this group is responsible for writing the TCPS and the TCPS interpretations). They were interested in the clinical trial and deception presentations in particular from CAREB-Ontario 2011</li><li>· PRE is currently working on revisions to the clinical trial chapter</li><li>· LW put in a request for interpretation for the clinical trials chapter on the website</li><li>· LW explained the interpretation for deception and re-consent as not always necessary (as it is not always practical)</li><li>· If re-consent would invalidate the data then it should not be used</li><li>· This is based on the notion that REBs are supposed to protect participants but also facilitate research</li><li>· Proportionality of risk also needs to be considered in cases</li></ul>	LW to meet with Maurice Feldman about autism studies and contact colleagues at York and Queens to obtain advice on processes for exercise and autism studies. LW to also contact Waterloo and McMaster about their current definition of a clinical trial and related processes. LW to circulate slides from University of Guelph presentation with the decision tree for clinical trials to all BREB members.  BR to research <a href="http://clinicaltrials.gov">clinicaltrials.gov</a> , contact colleague conducting exercise research at McMaster and talk to Maureen Murphy about intellectual property

		<p>of deception</p> <ul style="list-style-type: none"> <li>· Discussed preliminary feedback from CAREB-2011 feedback survey</li> <li>· Overall, feedback was quite good</li> <li>· The discussion went back to clinical trials</li> <li>· One of the presenters at CAREB-Ontario 2011 for clinical trials made a decision tree for navigating what is a “clinical trial”. This was discussed in detail</li> <li>· Many members found this decision tree helpful</li> <li>· While LW sent in a request for interpretation, the BREB struggled with what process is going to be followed in the interim</li> <li>· Main studies at Brock that may be hard to interpret as a clinical trial are some exercise and nutrition studies</li> <li>· Since the BREB is not receiving the same volume of applications as the SREB, a sub-committee to do research and put procedure/policy in place is needed</li> <li>· Question posed: How will the BREB define what is or is not a clinical trial? A discussion about this ensued</li> <li>· Suggested we should follow Waterloo – if the study does not fall under the definition of clinical trials by Health Canada then it is not a clinical trial</li> <li>· Others suggested to look at registry and see what types of research goes through as a clinical trial (clinicaltrials.gov)</li> <li>· Noted that some journals signed an agreement that they will not publish clinical trials that have not been registered</li> <li>· A discussion ensued around the value in registering research as a clinical trial versus not registering</li> <li>· Noted that selective publication of results was the core reason behind registration with Health Canada</li> <li>· Definition of clinical trial from the TCPS was discussed</li> <li>· Noted a policy needs to be written on this to clearly indicate what defines a clinical trial and what does not</li> <li>· Noted that clinical trial.gov is free to register but further noted it will cost the researcher in time to carry out the registration process</li> <li>· Noted that something needs to be written into the ethics application form to prompt researcher about clinical trials</li> <li>· Currently all autism studies go through SREB</li> <li>· Noted the need to break down the definition of a “clinical trial”</li> <li>· The effect of registering as a clinical trial on student projects was discussed</li> <li>· BREB members were encouraged to email if they found any useful information on this topic</li> <li>· Once policies/procedures are created, the BREB must discuss how to best educate researchers so they understand what is required and when</li> </ul> <p><b>University Spin Off Corporations</b></p> <ul style="list-style-type: none"> <li>· Norgen Biotek recently asked if the REB could review research proposals for research conducted at their facility</li> <li>· Discussed that Norgen Biotech publicly associates with Brock University and vice versa. As such, research at Norgen could be considered under the auspices or jurisdiction of Brock</li> <li>· However, it was also acknowledged that Norgen is a separate business from the institution</li> <li>· Concluded to inform researchers that the REB is still unclear about whether or not future reviews will be conducted (so precedent is not expected)</li> </ul>	<p>rights.</p> <p>MM and LW to put something together for the Chair of the Research and Scholarship Policy Committee (RSPC). Also, follow up is needed with the committee to define Brock’s “jurisdiction” and “auspices”.</p>
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4	<b>Educational Component</b>	<p><b>Emergent Designs</b></p> <ul style="list-style-type: none"> <li>· Noted that this educational component is more relevant for the SREB</li> <li>· Discussed that the new TCPS encourages REB's to recognize emergent design in research</li> <li>· LW explained emergent designs cannot always explain each step of the research up front</li> <li>· In some cases researchers may only be able to lay out the parameters of their research and focus at first</li> <li>· Some researchers submit to our Board in stages</li> <li>· All of the details are not always present at the start of research using emergent designs</li> <li>· Specified that researchers need room to have their work develop</li> </ul> <p><b>Alternatives to formal written consent</b></p> <ul style="list-style-type: none"> <li>· Explained that consent is a process</li> <li>· Recognizing that consent is about the participant being informed</li> <li>· The new document (TCPS) better recognizes verbal consent</li> <li>· Re-consent after deception was also discussed</li> <li>· Continuing consent was discussed</li> <li>· Cognitive and diminished capacity of research participants was discussed</li> </ul>	
5	<b>Other Business</b>		
6	<b>Adjourned</b>		