

TBRHSC REB Reviewer Information (REO to complete)			
REB #:	«Application_Number»		
Protocol Title:	«FirstOfName_of_Proposed_Research_Study»		
PI:	«PI_Title» «PI_First_Name» «PI_Last_Name»		
Reviewer Name:			
Review Type:	<input type="checkbox"/> Delegated	<input type="checkbox"/> Full Board	
Other review status:	Privacy Officer	<input type="checkbox"/> Pending	<input type="checkbox"/> Not required
	Joint Pharmacy & Therapeutics Committee	<input type="checkbox"/> Pending	<input type="checkbox"/> Not required
REB agenda date:	<input type="checkbox"/> N/A - delegated review	<input type="checkbox"/> December 2017	<input type="checkbox"/> April 2018
	<input type="checkbox"/> September 2017	<input type="checkbox"/> January 2018	<input type="checkbox"/> May 2018
	<input type="checkbox"/> October 2017	<input type="checkbox"/> February 2018	<input type="checkbox"/> June 2018
	<input type="checkbox"/> November 2017	<input type="checkbox"/> March 2018	
Study documents included:	Please refer to Section P of the REB Application form.		

**Reviewer to Complete**

REB Reviewer Attestation		
<input type="checkbox"/>	<b>I agree to act as an REB reviewer for this study</b>	
<input type="checkbox"/>	<b>I do not agree to complete the review of this study because:</b>	
<input type="checkbox"/>	<b>I have a real or perceived conflict of interest with reviewing this study (Specify):</b>	
<input type="checkbox"/>	<b>Other (Specify):</b>	
<b>Name:</b>	<b>Signature:</b>	<b>Date:</b>

Instructions				
<b>Legend:</b>	<b>IDK =</b>	<b>N/A =</b>	<b>Y=</b>	<b>N=</b>
	Do not know: Indicate in comments section if you have questions.	Not Applicable to this research project	Yes, this is adequately explained in the REB application package	No, this is not adequately explained in the REB application package
Please complete this checklist as you review this application package. Please indicate whether the researcher has given adequate consideration and safeguards to the following areas of concern				
<b>Describe issues that do not meet the checkbox criteria in the provided comments boxes. Please frame your comments as questions or comments that can be directed to the PI</b>				
Your review is based upon all of the documents included in the review package, although the REO strives to ensure consistency among all documents before sending for review, please ensure to note any inconsistencies between the study documents and REB application.				

## Section A

Description of Research Team	IDK	N/A	Y	N
In your opinion, is the research team described in the application appropriately qualified to complete the study as described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to the study team for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section B

Research Project / Protocol Title/ Overall Description of Research Project/Protocol	IDK	N/A	Y	N
Considering the complete application, is the research question clearly stated?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Are the research objectives/endpoints clearly Articulated?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
In your opinion, will the research generate knowledge that could reasonably lead to improvements in health and well being?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to the study title/question/summary for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section C:

Application Overview	IDK	N/A	Y	N
Do you agree with the researcher's assessment as to whether the project is low risk as defined by TCSP2?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Looking at the REB application and the study documents, do you feel that the researcher has provided an adequate description of ethics considerations involved in the research?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Did the researcher accurately identify the use of any vulnerable participants?	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
What vulnerable participants study does the study include?	<input type="checkbox"/>	<input type="checkbox"/> None <input type="checkbox"/> Children <input type="checkbox"/> Elderly <input type="checkbox"/> Limited capacity <input type="checkbox"/> Other: Specify _____		
If the study involves vulnerable participants, is the justification for their use clearly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there additional safeguards in place sufficient enough to protect vulnerable populations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In your opinion, will participants be treated with dignity and respect?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
For research involving aboriginal populations, did the researcher provide sufficient information to show adherence to Chapter 9 of TCPS2?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that previous decisions made by other REBs or regulatory authorities for the proposed study have been appropriately accounted for and do not require further investigation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Given the nature of the research and the level of scientific review that occurred prior to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

submission to the REB, do you feel that sufficient review has occurred?				
<b>Key comments / concerns and issues related to the application overview for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

<b>Section D: Research Design &amp; Methodology</b>	<b>IDK</b>	<b>N/A</b>	<b>Y</b>	<b>N</b>
Is the methodology/design described in sufficient detail?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the methodology / design adequate to answer the research question?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the data analysis adequately described and appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the sample size justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at the REB application and the study documents, do you feel that the researcher has provided an adequate description of ethics considerations involved in the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to research design and methodology for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

<b>Section E</b>				
<b>Local Implementation of Project</b>	<b>IDK</b>	<b>N/A</b>	<b>Y</b>	<b>N</b>
Is the local implementation plan ethical?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the researcher made adequate and appropriate customizations to the protocol for implementation at TBRHSC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to the local implementation of project for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

<b>Section F</b>				
<b>Recruitment of Participants Involved in the Research</b>	<b>IDK</b>	<b>N/A</b>	<b>Y</b>	<b>N</b>
Do you believe that the selection of participants / charts / samples / etc is fair and equitable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at the study documents, are inclusion / exclusion criteria equitable (ie. no inappropriate exclusions on basis of race, age, gender, etc)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you believe that the threat of coercion is minimized in the proposed recruitment process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Recruitment of Participants Involved in the Research for discussion</b>				

**(Please frame your comments as questions or comments that can be directed to the PI):**

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**Section G**

Informed Consent	IDK	N/A	Y	N
Do you feel that the researcher sufficiently addressed all of the required elements for the informed consent form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that the process described to obtain and document consent is ethical?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a consent waiver is being requested, do you feel that this is appropriately justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is it clear that the decision not to participate will not impact the participants overall care at TBRHSC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that the research participant is given an adequate enough amount of time to deliberate whether to provide consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that research has selected an appropriate person to administer consent? Is the threat of coercion minimized appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that informed consent will be sufficiently sought from each prospective participant or the participant's legally authorized representative? If informed consent is not required, select N/A.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is it clear how a participant can request withdrawal?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the withdrawal process ethical?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Key comments / concerns and issues related to Informed Consent for discussion (Please frame your comments as questions or comments that can be directed to the PI):**

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**Section H**

Potential Benefits	IDK	N/A	Y	N
Do you feel this research will benefit to participants, the scientific community, and/or society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel that the benefits appropriately outweigh the risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Key comments / concerns and issues related to Potential Benefits for discussion (Please frame your comments as questions or comments that can be directed to the PI):**

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## Section I

Potential Risks	IDK	N/A	Y	N
Based on the proposal, are risks to participants minimized by sound research design?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are risks to participants reasonable in relation to anticipated benefits?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are risks to participants reasonable in relation to the importance of the knowledge that may reasonably be expected to result?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are adequate provisions made to protect the privacy of participants and to maintain the confidentiality of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Given the associated risks, is the compensation proposed for study participation reasonable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are the steps described to minimize the risks associated with the study sufficient?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Potential Risks for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section J

Confidentiality	IDK	N/A	Y	N
Do you feel that the researcher has put in sufficient measures to ensure the confidentiality of the research participant is maintained throughout the course of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Confidentiality for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section K

Personal Health Information	IDK	N/A	Y	N
Is the justification for the collection of identifiable information sufficient enough to approve its collection?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Personal Health Information for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section L

Section L				
Data Management and Storage	IDK	N/A	Y	N
Is the data management and storage plan sufficient to ensure data quality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the data management and storage plan sufficient to ensure participant confidentiality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Data Management and Storage for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section M

Section M				
Funding Sources	IDK	N/A	Y	N
Is the budget justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Based on the payments made to the researcher, is there evidence of actual or potential financial conflicts of interest?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the budget of sufficient amount and duration to support the length of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Funding Sources for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

## Section N

Section N				
Declaration of COI	IDK	N/A	Y	N
If any conflicts of interest were disclosed by the Principal Investigator or Co-Investigators, has the researcher sufficiently identified the potential consequences?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If any conflicts of interest were disclosed by the Principal Investigator or Co-Investigators, are the additional protections in place sufficient to mitigate the risk of the conflict?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Declaration of COI for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

Section O				
Clinical Trial/ Medical Devices Studies	IDK	N/A	Y	N
Is this study a Clinical Trial? If not applicable, skip to next section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the Data Safety Monitoring plan suitable for the type of study proposed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If stopping rules or interim analyses are required, are they adequate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you believe the research team has provided enough evidence to ensure that the trial will be conducted in accordance with Good Clinical Practices and TCPS 2?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to Clinical Trial/ Medical Devices Studies for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

Section P				
List of Documentation for this Application	IDK	N/A	Y	N
Did you consider in your review all of the versions of the documents listed in Section P of the application?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Key comments / concerns and issues related to List of Documentation for this Application for discussion (Please frame your comments as questions or comments that can be directed to the PI):</b>				

**Section Q: Overall Recommendations**

**I have reviewed the documents described in the attached TBRHSC REO Prescreen form and make the following overall recommendation: *(Select one option)***

**OPTION 1:**

**This project requires additional review and additional review should be performed by: *(Select all that apply)***

- |   |  |
|---|--|
| <input type="checkbox"/> Those knowledgeable in the relevant law  | <input type="checkbox"/> Mariette Brennan<br><input type="checkbox"/> Joy Wakefield<br><input type="checkbox"/> Jack Jamieson  |
| <input type="checkbox"/> A community member with no affiliation with the institution                                    | <input type="checkbox"/> Bill Gregorash<br><input type="checkbox"/> Claude Camirand  |
| <input type="checkbox"/> Those knowledgeable in relevant research disciplines, fields and methodologies and a physician | <input type="checkbox"/> Salima Oukachbi<br><input type="checkbox"/> Valentina Peeva<br><input type="checkbox"/> Ghazala Basir   |
| <input type="checkbox"/> Those Knowledgeable in relevant research disciplines, fields and methodologies                 | <input type="checkbox"/> Shelley Chisholm<br><input type="checkbox"/> Peter Voros<br><input type="checkbox"/> Simon Lees<br><input type="checkbox"/> Andrea Raynak<br><input type="checkbox"/> Trina Diner |
| <input type="checkbox"/> Those Knowledgeable in ethics  | <input type="checkbox"/> Michelle Allain   |
| <input type="checkbox"/> Those knowledgeable in drugs and drug safety   | <input type="checkbox"/> Joint Pharmacy and Therapeutics Committee   |
| <input type="checkbox"/> Those Knowledgeable in privacy   | <input type="checkbox"/> Privacy Officer – Mieke De Roover   |
| <input type="checkbox"/> Those Knowledgeable on matters related First Nations, Inuit and Métis Peoples of Canada        | <input type="checkbox"/> Helen Cromarty<br><input type="checkbox"/> Eli Nix  |
| <input type="checkbox"/> Those Knowledgeable on matters related to medical physics                                      | <input type="checkbox"/> Medical Physicist - Bans Arjune   |
| <input type="checkbox"/> Those Knowledgeable on matters related to emergency and trauma medicine                        | <input type="checkbox"/> Fredric Sarrazin  |
| <input type="checkbox"/> Those Knowledgeable on matters related to imaging Magnetic resonance imaging methods           | <input type="checkbox"/> Mitch Albert  |
| <input type="checkbox"/> Those Knowledgeable on community health or epidemiology  | <input type="checkbox"/> Kevin Willison  |
| <input type="checkbox"/> Those Knowledgeable on matters related to behavioural sciences and neuro-imaging               | <input type="checkbox"/> Jane Lawrence-Dewar   |
| <input type="checkbox"/> Those knowledgeable in the patient experience  | <input type="checkbox"/> Patient and family advisor  |

**OPTION 2:**

**This project does not require additional review: *(Select one)***

- Approve the project as submitted
- Request minor clarifications / revisions that I would like the REB Chair to review in order to determine if responses are complete and satisfactory.
- Request minor clarifications that I would like to review in order to determine if responses are complete and satisfactory.
- Request major clarifications that the full REB should review in order to determine if responses are complete and satisfactory
- This project should be rejected by the REB and it should not be approved.

**Additional comments**



