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:	☐ Delegated	☐ Full Board	
Other review status:	Privacy Officer	☐ Pending	☐ Not required
	Joint Pharmacy & Therapeutics Committee	☐ Pending	☐ Not required
REB agenda date:	☐ N/A - delegated review ☐ September 2017 ☐ October 2017 ☐ November 2017	☐ December 2017 ☐ January 2018 ☐ February 2018 ☐ March 2018	☐ April 2018 ☐ May 2018 ☐ June 2018
Study documents included:	Please refer to Section P of the REB Application form.		

Reviewer to Complete

REB Reviewer Attestation		
☐ ***I agree to act as an REB reviewer for this study***		
☐ ***I do not agree to complete the review of this study because:***		
☐ ***I have a real or perceived conflict of interest with reviewing this study (Specify):***		
☐ ***Other (Specify):***		
Name:	**Signature:**	**Date:**

Instructions				
Legend:	**IDK =** Do not know: Indicate in comments section if you have questions.	**N/A =** Not Applicable to this research project	**Y=** Yes, this is adequately explained in the REB application package	**N=** 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

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

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?	☐	☐	☐	☐
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):				

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?	☐		☐	☐
Are the research objectives/endpoints clearly Articulated?	☐		☐	☐
In your opinion, will the research generate knowledge that could reasonably lead to improvements in health and well being?	☐		☐	☐
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):				

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?	☐		☐	☐
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?	☐		☐	☐
Did the researcher accurately identify the use of any vulnerable participants?	☐		☐	☐
What vulnerable participants study does the study include?	☐	☐None ☐Children ☐Elderly ☐Limited capacity ☐Other: Specify_____		
If the study involves vulnerable participants, is the justification for their use clearly stated?	☐	☐	☐	☐
Are there additional safeguards in place sufficient enough to protect vulnerable populations?	☐	☐	☐	☐
In your opinion, will participants be treated with dignity and respect?	☐	☐	☐	☐
For research involving aboriginal populations, did the researcher provide sufficient information to show adherence to Chapter 9 of TCPS2?	☐	☐	☐	☐
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?	☐	☐	☐	☐
Given the nature of the research and the level of scientific review that occurred prior to	☐	☐	☐	☐

submission to the REB, do you feel that sufficient review has occurred?				
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):				

Section D: Research Design & Methodology	**IDK**	**N/A**	**Y**	**N**
Is the methodology/design described in sufficient detail?	☐	☐	☐	☐
Is the methodology / design adequate to answer the research question?	☐	☐	☐	☐
Is the data analysis adequately described and appropriate?	☐	☐	☐	☐
Is the sample size justified?	☐	☐	☐	☐
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?	☐	☐	☐	☐
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):				

Section E				
Local Implementation of Project	**IDK**	**N/A**	**Y**	**N**
Is the local implementation plan ethical?	☐	☐	☐	☐
Has the researcher made adequate and appropriate customizations to the protocol for implementation at TBRHSC?	☐	☐	☐	☐
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):				

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

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

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 from?	☐	☐	☐	☐
Do you feel that the process described to obtain and document consent is ethical?	☐	☐	☐	☐
If a consent waiver is being requested, do you feel that this is appropriately justified?	☐	☐	☐	☐
Is it clear that the decision not to participate will not impact the participants overall care at TBRHSC?	☐	☐	☐	☐
Do you feel that the research participant is given an adequate enough amount of time to deliberate whether to provide consent?	☐	☐	☐	☐
Do you feel that research has selected an appropriate person to administer consent? Is the threat of coercion minimized appropriately?	☐	☐	☐	☐
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.	☐	☐	☐	☐
Is it clear how a participant can request withdrawal?	☐	☐	☐	☐
Is the withdrawal process ethical?	☐	☐	☐	☐
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):				

Section H				
Potential Benefits	**IDK**	**N/A**	**Y**	**N**
Do you feel this research will benefit to participants, the scientific community, and/or society?	☐	☐	☐	☐
Do you feel that the benefits appropriately outweigh the risks?	☐	☐	☐	☐
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):				

Section I				
Potential Risks	**IDK**	**N/A**	**Y**	**N**
Based on the proposal, are risks to participants minimized by sound research design?	☐	☐	☐	☐
Are risks to participants reasonable in relation to anticipated benefits?	☐	☐	☐	☐
Are risks to participants reasonable in relation to the importance of the knowledge that may reasonably be expected to result?	☐	☐	☐	☐
Are adequate provisions made to protect the privacy of participants and to maintain the confidentiality of the data?	☐	☐	☐	☐
Given the associated risks, is the compensation proposed for study participation reasonable?	☐	☐	☐	☐
Are the steps described to minimize the risks associated with the study sufficient?	☐	☐	☐	☐
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):				

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?	☐	☐	☐	☐
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):				

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?	☐	☐	☐	☐
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):				

Section L				
Data Management and Storage	**IDK**	**N/A**	**Y**	**N**
Is the data management and storage plan sufficient to ensure data quality?	☐	☐	☐	☐
Is the data management and storage plan sufficient to ensure participant confidentiality?	☐	☐	☐	☐
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):				

Section M				
Funding Sources	**IDK**	**N/A**	**Y**	**N**
Is the budget justified?	☐	☐	☐	☐
Based on the payments made to the researcher, is there evidence of actual or potential financial conflicts of interest?	☐	☐	☐	☐
Is the budget of sufficient amount and duration to support the length of the study?	☐	☐	☐	☐
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):				

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?	☐	☐	☐	☐
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?	☐	☐	☐	☐
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):				

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.	☐	☐	☐	☐
Is the Data Safety Monitoring plan suitable for the type of study proposed?	☐	☐	☐	☐
If stopping rules or interim analyses are required, are they adequate?	☐	☐	☐	☐
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?	☐	☐	☐	☐
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):				

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?	☐	☐	☐	☐
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):				

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)*

☐ Those knowledgeable in the relevant law	☐ Mariette Brennan ☐ Joy Wakefield ☐ Jack Jamieson
☐ A community member with no affiliation with the institution	☐ Bill Gregorash ☐ Claude Camirand
☐ Those knowledgeable in relevant research disciplines, fields and methodologies and a physician	☐ Salima Oukachbi ☐ Valentina Peeva ☐ Ghazala Basir
☐ Those Knowledgeable in relevant research disciplines, fields and methodologies	☐ Shelley Tees ☐ Peter Voros ☐ Simon Lees ☐ Andrea Raynak ☐ Trina Diner
☐ Those Knowledgeable in ethics	☐ Michelle Allain
☐ Those knowledgeable in drugs and drug safety	☐ Joint Pharmacy and Therapeutics Committee
☐ Those Knowledgeable in privacy	☐ Privacy Officer – Mieke De Roover
☐ Those Knowledgeable on matters related First Nations, Inuit and Métis Peoples of Canada	☐ Helen Cromarty ☐ Eli Nix
☐ Those Knowledgeable on matters related to medical physics	☐ Medical Physicist - Bans Arjune
☐ Those Knowledgeable on matters related to emergency and trauma medicine	☐ Fredric Sarrazin
☐ Those Knowledgeable on matters related to imaging Magnetic resonance imaging methods	☐ Mitch Albert
☐ Those Knowledgeable on community health or epidemiology	☐ Kevin Willison
☐ Those Knowledgeable on matters related to behavioural sciences and neuro-imaging	☐ Jane Lawrence-Dewar
☐ Those knowledgeable in the patient experience	☐ 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 rejected by the REB and it should not be approved.

Additional comments