TBRHSC REO Prescreen			
TBRHSC REB #:	«Application_Number»		
Study Title:	«FirstOfName_of_Proposed_Research_Study»		
Principal Investigator:	«PI_Title» «PI_First_Name» «PI_Last_Name»	«PI_Primary_Affiliation»	«PI_Department»
	Name:	**Organization:**	**Position:**
Qualified Investigator: (If required)			
Study Sponsor / Funding Agency:			

Authorization Status:	**N/A**	**Pending**	**Complete**	**Comments:**
Registered with Research Program		☐	☐	
Academic Institution Approval	☐	☐	☐	
Joint Pharmacy and Therapeutics Approval	☐	☐	☐	**Date reviewed:**
Health Canada NOL	☐	☐	☐	
Health Canada ITA approval	☐	☐	☐	
Approval by Lakehead university REB:	☐	☐	☐	
Approval by another SJCG REB:	☐	☐	☐	
Approval by another REB Specify:	☐	☐	☐	
Authorization by Research VPR		☒		*The project shall receive final authorization by the TBRHSC Research Program prior to the conduct of any research-related activity.*

Study Document	**N/A**	**Version**	**Minimum Standard Met?**		**Consistent with other documents?**		**Comments**
			Y	**N**	**Y**	**N**	
Signed and dated REB application form			☐	☐	☐	☐	
Protocol with all appendices			☐	☐	☐	☐	☐ Must meet GCP
Budget			☐	☐	☐	☐	
Informed Consent form	☐		☐	☐	☐	☐	
Data Abstraction form	☐		☐	☐	☐	☐	☐ Must meet PHIPPA
Questionnaires intended for participants (eg. Case report forms, diaries)	☐		☐	☐	☐	☐	
Recruitment material	☐		☐	☐	☐	☐	

Specify:							
Investigator's Brochure	☐		☐	☐	☐	☐	
Other Specify:	☐		☐	☐	☐	☐	
Other Specify:	☐		☐	☐	☐	☐	

Were all required study documents provided?	☐ **Yes**	☐ **No**
Key Comments related to documents		

Section A: Description of Research Team	**N/A**	**Y**	**N**
Based on the complete application, did the researcher accurately include all of the necessary individuals in this section?		☐	☐
Has TCPS 2 training be confirmed for all individuals listed on the REB application?		☐	☐
Key comments / concerns and issues related to the study team for consideration:			
Research Program will ensure all investigators and study team members have competed TCPS2 certification and that their certificate is on file with the organization.			

Section B: Research Project / Protocol Title / Overall Description of Research Project/Protocol	**N/A**	**Y**	**N**
Did the researcher complete all sections accurately?		☐	☐
Was the question stated in a question format that indicates who is being studied, what the intervention is (if any), what are the comparison groups (if any), the outcome measures and the methodology to be used?		☐	☐
Is the overall summary fewer than 300 words, in 12 point font and written in lay terms that all REB members will understand?		☐	☐
Does the overall summary list the aim and/or objectives of the study?		☐	☐
Does the overall summary provide justification for the study?		☐	☐
Is the information described in the REB application consistent with the information described in the study documents?		☐	☐
Key comments / concerns and issues related to the study title/question/summary for consideration:			

Section C: Application Overview	**N/A**	**Y**	**N**
Did the researcher correctly identify if organizations other than SJCG or TBRHSC are involved?		☐	☐
Did the researcher correctly identify if the study requires research ethics review elsewhere:		☐	☐
If yes, did they indicate the status of any applications?	☐	☐	☐
Did the researcher provide all significant previous decisions by other REBs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account?	☐	☐	☐
Did the researcher indicate if the project has received negative decisions previously, and if so, were reasons for any previous negative decisions provided?	☐	☐	☐

Section C: Application Overview	N/A	Y	N
Did the researcher indicate if the protocol has been peer reviewed for scientific merit?		☐	☐
If the research has been reviewed, did they attach a copy of the scientific merit review?	☐	☐	☐
Given the nature of the research, has the research undergone an appropriate level of scientific merit review prior to submission to the REB?		☐	☐
Based on the information provided, did the researcher correctly assign a level of risk to the study?		☐	☐
Level of Risk Assigned:	☐ High ☐ Low		
Did the researcher correctly identify any vulnerable population groups from which participants are being recruited?	☐	☐	☐
Potentially vulnerable populations identified:	☐ None ☐ Children ☐ Elderly ☐ Participants Who Lack the Capacity to Consent for Themselves ☐ Other Specify:		
For research involving aboriginal populations, did the researcher provide detailed information to show adherence to Chapter 9 of TCPS2?	☐	☐	☐
Did the researcher correctly identify if the research is a partial fulfillment of academic requirements?	☐	☐	☐
If the research is a partial fulfillment of academic requirements, did the researcher provide adequate details about the Program, supervisor & Institution?	☐	☐	☐
For projects involving TBRRI or TBRHSC, has the project been registered with the Clinical Research Program and is it in the pre-initiation stage?	☐	☐	☐
For projects involving any medication, has the researcher correctly identified that Joint Pharmacy and Therapeutics approval is required?	☐	☐	☐
Did the researcher indicate correctly if this is an industry-sponsored research initiative?	☐	☐	☐
If the study is funded by industry, did the researcher provide contact information for invoicing purposes?	☐	☐	☐
Invoicing through:	☐ TBRHSC – Clinical Trials ☐ TBRHSC – Clinical Research Program ☐ Other Specify*:*		
Key comments / concerns and issues related to the application overview for consideration:			

Section D: Research Design & Methodology	N/A	Y	N
Is Section D of the REB application form written for a broad audience and are all acronyms and technical terminology defined?		☐	☐
Has the researcher included a clear definition of the study design?		☐	☐
Has the researcher included in this section a summary of the timing and sequence of events involved in the study? This could be a non-technical summary, synopsis, or diagrammatic representation of the protocol.		☐	☐
If the study involves direct participation by participants, has the researcher included or referenced a section in the protocol that provides details about the timing and sequence of events involved in each study visit? (This should include details of what happens when	☐	☐	☐

Section D: Research Design & Methodology	N/A	Y	N
participants are prematurely withdrawn or withdraw from the study)			
If the study involves direct participation by participants, are all procedures in which a participant is involved clearly described from the perspective the patient?	☐	☐	☐
Has the researcher clearly indicated the number of groups included?		☐	☐
Has the researcher clearly indicated if a control group will be used and, if so, identified the nature of the control group?		☐	☐
Was sample size for each group justified? (in app or protocol)		☐	☐
Does the research question / study objectives justify the collection of personal demographic information and personal health information?	☐	☐	☐
If the study involves different groups, does the researcher clearly identify what procedures, if any, differ between groups?	☐	☐	☐
Does the researcher clearly identify the data analysis techniques that will be used?		☐	☐
This should include details of what happens in the case of missing data and data collected on participants who are withdrawn or withdraw prematurely.		☐	☐
Is the information about the research design and methodology consistent across all study documents and the REB application form?		☐	☐
Key comments / concerns and issues related to research design and methodology for consideration:			

Section E: Local Implementation of Project	N/A	Y	N
Did the researcher provide a start and end date for the study? Is it realistic?		☐	☐
Did the researcher appropriately identify if TBRHSC and SJCG would be involved?		☐	☐
Did the researcher include a project timeline detailing major milestones and estimating dates? (Recruitment, First data point collected, Last data point collected, Data analysis start, Data analysis completion, dissemination of results)		☐	☐
Did the researcher identify if the protocol will be customized to implement at TBRHSC and have they appropriately identified all instances to be customized?		☐	☐
Has the researcher clearly identified what programs and services at TBRHSC will be affected by this project and how?	☐	☐	☐
Has the researcher clearly identified what TBRHSC resources (staff, equipment, etc) are required to implement the study?	☐	☐	☐
Is the researcher working with the Clinical Research Program to ensure that programs and services are on board and that required TBRHSC resources are available?	☐	☐	☐
Has all material to be provided to the participant (consent forms, recruitment material, etc.) been localized to TBRHSC?	☐	☐	☐
Key comments / concerns and issues related to the local implementation of project for consideration:			

Section F: Recruitment of Participants Involved in the Research	N/A	Y	N
Has the researcher appropriately selected whether the project will involve direct participation of human participants?		☐	☐
Has the researcher appropriately selected whether the project will involve the review of health records?		☐	☐
Has the researcher estimated the number of participants to be recruited (enrolled) at TBRHSC?	☐	☐	☐
If only a portion of eligible (available population) participants will be selected, is the selection	☐	☐	☐

Section F: Recruitment of Participants Involved in the Research	N/A	Y	N
process outlined?			
Did the researcher clearly describe how potential participants / charts /samples / etc will be identified by the research team as eligible in this section or reference the section of the protocol detailing this information?		☐	☐
For studies involving direct human participation, did the researcher clearly describe how the potential participants will be approached to offer them participation in the study?	☐	☐	☐
Is this section consistent with all other study documents?		☐	☐
Did the researcher provide a copy of all material to be used (including advertisements) for the recruitment of potential research participants?	☐	☐	☐
Key comments / concerns and issues related to the Recruitment of Participants Involved in the Research for consideration:			

Section G: Informed Consent	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Did the researcher detail who will be administering consent?	☐	☐	☐
Did the researcher detail how much time the participant will be given to consider providing informed consent?	☐	☐	☐
Did the researcher include a detailed description of the process used to obtain and document consent and does it meet TCPS2?	☐	☐	☐
If this is a clinical trial, does the detailed description of the process used to obtain and document consent meet GCP?	☐	☐	☐
If a consent waiver is being requested, did the researcher provide a justification that is consistent with TCPS2?	☐	☐	☐
If the study involves a participant who is not able to consent on their own behalf, did the researcher detail a process regarding if and how consent will be obtained?	☐	☐	☐
If applicable, did the researcher detail how ongoing consent will be maintained throughout the study? As relevant, this should also take into consideration if a participant's ability to provide consent changes throughout the course of a study.	☐	☐	☐
If applicable, has the researcher described in sufficient detail the process by which participants can withdraw consent to participate in a study? Is this consistent across all study documents?	☐	☐	☐
If the participant can withdraw, has the researcher provided details about what will happen to all previously collected data?	☐	☐	☐
Will withdrawal include withdrawal of all previously collected information?	☐	☐	☐
If applicable, did the researcher include a copy of the informed consent form (clearly identified, dated and on TBRHSC letterhead) in the language(s) understood by the potential research participants?	☐	☐	☐
If applicable, does the informed consent form meet the minimum requirements for TCPS2?	☐	☐	☐
If the study is a clinical trial, does the informed consent form meet the minimum requirements for GCP?	☐	☐	☐
Key comments / concerns and issues related to the Informed Consent for consideration:			

Section H: Potential Benefits	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Did the researcher provide a description of the proposed benefits to participants, the scientific community, and/or society?	☐	☐	☐
If there is no benefit to the participants, did the researcher state this explicitly?	☐	☐	☐
Key comments / concerns and issues related to the Potential Benefits for consideration:			

Section I: Potential Risks	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Did the research clearly identify all potential physical, physiological, social and financial risks a participant could anticipate?		☐	☐
Did the researcher clearly describe the likelihood and severity of all potential physical, physiological, social and financial risks a participant could anticipate?		☐	☐
If the research involves a psychological or physiological risk, did the researcher outline a process by which an individual who is appropriately qualified will address any negative impact on a participant as a result of their participation in the study?	☐	☐	☐
If the study involves deception, did the researcher provide a justification for its use and a detailed debriefing procedure?	☐	☐	☐
If applicable, did the researcher include a description of the arrangements for indemnity related to the project and is it consistent across all study documents?	☐	☐	☐
If applicable, did the researcher include a description of the arrangements for insurance coverage for research participants?	☐	☐	☐
If the participant is exposed to any risk the researcher justifies financial compensation for, did the researchers include a statement describing these reimbursements?	☐	☐	☐
Has the researcher identified whether there is foreseeable risk of identifying clinically significant incidental finding during the course of the study?		☐	☐
If there is foreseeable risk of identifying clinically significant incidental findings during the course of the study, has the researcher provided a description of procedures they will follow that are detailed enough for consideration by the REB?	☐	☐	☐
Does the consent form clearly identify all of the proposed risks and the mitigation strategy in way that the participant can be expected to fully comprehend?	☐	☐	☐
Key comments / concerns and issues related to the Potential Risks for consideration:			

Section J: Confidentiality	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Did the researcher identify if and when individual research results will be disclosed to third parties? This should take into consideration if members of the REB, TBRHSC, the sponsor regulatory agencies will have access to participant data.	☐	☐	☐
Did the researcher provide sufficient details about the steps that will be taken to ensure confidentiality of the data for consideration by the REB?	☐	☐	☐
Did the researcher provide sufficient details about how confidentiality will be maintained in research reports and articles?	☐	☐	☐
Key comments / concerns and issues related to the Confidentiality for consideration:			

Section K: Personal Health Information	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Did the researcher complete all sections accurately?	☐	☐	☐
Did the researcher describe <u>all sources</u> of personal health information: electronic medical records, paper charts, interviews, identifying surveys?	☐	☐	☐
Is the data abstraction form attached as an appendix to the REB application?	☐	☐	☐
Is it clear who will have access to the data, and for what purpose?		☐	☐
Did the researcher describe in sufficient detail a justification for why identifiable information will be collected?	☐	☐	☐
Key comments / concerns and issues related to the Personal Health Information for consideration:			

Section L: Data Management and Storage	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Has the researcher described the electronic data security measures? (e.g password protected, encrypted files)	☐	☐	☐
If identifying information is required, has the research team described its process to de-identify the data? (eg. the creation of a Key)	☐	☐	☐
Has the short term storage of study data been described? Including both electronic and hard copy storage.	☐	☐	☐
Has the long term storage plan been described?	☐	☐	☐
Has a data destruction plan been outlined?	☐	☐	☐
Key comments / concerns and issues related to the Data Management and Storage for consideration:			

Section M: Funding Sources		N/A	Y	N
Did the researcher complete all sections accurately?			☐	☐
Looking at the complete application, has the identity of who is funding the study clear?			☐	☐
The study is funded by:	☐ Industry ☐ Cooperative Group ☐ Grant ☐ Internal Funds ☐ Student Stipend Specify:			
Looking at the complete application, has the identity of the organization administering the funds been clearly identified?		☐	☐	☐
The organization administering the funds is:	☐ TBRHSC – Clinical Trials ☐ TBRHSC – Clinical Research Program ☐ Other *Specify:*			
Looking at the complete application, can you tell if the study is US federally funded or supported?			☐	☐
Did the researcher include a detailed budget that itemizes all costs associated with each phase of the study?			☐	☐
Is it clearly indicated if the research team will be paid for administering the trial?			☐	☐

Section M: Funding Sources	N/A	Y	N
For clinical trials, did the researcher identify the main study sponsor? (The individual, corporate body, institution or organization that is conducting a clinical trial)	☐	☐	☐
For clinical trials, did the researcher provide contact information for the main study sponsor?	☐	☐	☐
For Division 5 regulated clinical trials, did the researcher identify who is responsible for filing regulatory submissions with Health Canada?	☐	☐	☐
Did the researcher indicate whether a contract research organization involved?	☐	☐	☐
For clinical trials, did the researcher provide contact information for the contract research organization involved?	☐	☐	☐
Key comments / concerns and issues related to the Funding Sources for consideration:			

Section N: Declaration of COI	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
If any conflicts of interest were disclosed by the Principal Investigator or Co-Investigators, has the researcher described the consequences and additional protections in place to mitigate the risk of the conflict?	☐	☐	☐
Key comments / concerns and issues related to the Declaration of COI for consideration:			

Section O: Clinical Trial/ Medical Devices Studies	N/A	Y	N
Is this study a clinical trial? If no, skip to next section.		☐	☐
Did the researcher complete all sections accurately?	☐	☐	☐
Does the Research team include individuals with the required local credentials to conduct the project? (e.g a qualified investigator)	☐	☐	☐
Is the study registered with www.clinicaltrials.gov *or another suitable registry? (check online)*	☐	☐	☐
If a Health Canada No Objection Letter and / or a Health Canada Investigational Testing Authorization is required, was it provided?	☐	☐	☐
Does the Research team have the required local credentials to conduct project? (e.g a qualified investigator)	☐	☐	☐
If a DSMB is required, has the researcher described a non-affiliated DSMB?	☐	☐	☐
Has the researcher indicated if an interim analysis is planned for this study?	☐	☐	☐
Are there stopping rules outlined in the research plan?	☐	☐	☐
Given the complete application, did the researcher provide contact information for the main study sponsor?	☐	☐	☐
For Division 5 regulated clinical trials, did the researcher identify who is responsible for filing regulatory submissions with Health Canada?	☐	☐	☐
Given the complete application, did the researcher indicate whether a contract research organization involved?	☐	☐	☐
	CRO:		
Key comments / concerns and issues related to the Clinical Trial/ Medical Devices Studies for consideration:			

Section P: List of Documentation for this Application	N/A	Y	N
Did the researcher complete all sections accurately?		☐	☐
Are version dates or numbers indicated for each appendix?	☐	☐	☐

Section P: List of Documentation for this Application	N/A	Y	N
Do the document titles and version dates match those submitted?	☐	☐	☐
Key comments / concerns and issues related to the List of Documentation for this Application for consideration:			

Section Q: Overall Recommendations		
I completed the review as described above and make the following recommendation: ☐ Return application to researcher to address recommendations ☐ Submit complete application to REB chair for consideration		
Name:	Signature:	Date: