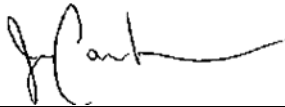




<b>Section 400:</b>	<b>Review of Research</b>
<b>Title:</b>	<b>Criteria for GREB Ethical Clearance</b>
<b>SOP Code:</b>	<b>404.002</b>
<b>Effective Date:</b>	<b>2020DEC14</b>

## Site Approvals

Signature of Responsible Individual:		
Manager , Research Ethics Compliance		Date:
	Name: Jennifer Couture	
Approval Authority:		
Chair, GREB		Date:
	Name: Dr. Dean Tripp	
Approval Authority:		
Director, Research Ethics Compliance		Date:
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

This SOP describes the minimum requirements that research proposals involving human participants must meet to receive ethics clearance by the GREB, independent of the review pathway (i.e. full board or delegated review).

## 2.0 SCOPE

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB's oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and

administrative research conducted under the auspice of Queen's University. The scope of GREB's oversight is limited to those activities defined in the TCPS 2 as "research" involving "human participants."

### **3.0 RESPONSIBILITIES**

All GREB members and GREB office personnel are responsible for ensuring that the requirements of this SOP are met.

GREB members are responsible for determining whether or not the research meets the criteria for ethics clearance.

### **4.0 DEFINITIONS**

See Glossary of Terms.

### **5.0 PROCEDURES**

All research involving human participants must meet certain criteria before GREB Ethics Clearance may be granted. Initial GREB Ethics Clearance of the research is based on assessment of a complete submission to the GREB. GREB and/or GREB office personnel may ask researchers for additional information as necessary.

Following initial review of the research, GREB full board or delegated reviewers should be prepared to make a determination as to whether or not the proposed research satisfies research ethics standards as set out in the TCPS 2 , such that GREB Research Ethics Clearance can be issued.

In addition to GREB Ethics Clearance, the requirements of Queen's University must also be met before the research can begin (e.g., department approvals, adequate resources).

Participant recruitment/registration, pilot studies, obtaining informed consent, and access or collection of data cannot start prior to receiving written ethical clearance by GREB.

## **5.1 Minimal Criteria for Ethical Clearance of Research**

For the research to receive GREB Ethics Clearance, GREB takes the following criteria into consideration:

- 5.1.1 The electronic application form has been submitted by the researchers or their designee who is qualified to conduct the research;
- 5.1.2 The purpose of the study is clearly defined and all supporting documentation attached;
- 5.1.3 The methodology appears sound and capable of answering the research questions;
- 5.1.4 Time requirement of participants for each session, as well as the total time requirement is explicitly stated;
- 5.1.5 Disclosure of any financial interest or potential Conflicts of Interest (COIs) and sufficient information to ensure any conflicts can be identified, minimized, or otherwise managed is included;
- 5.1.6 The sample size for participant recruitment is explained;
- 5.1.7 The selection of participants is equitable, ensuring the risks and benefits from research are justly distributed. In making this assessment, GREB will take into account the purpose of the research and the research setting.
- 5.1.8 When some or all of the participants have been inappropriately excluded from research historically as per the TCPS 2 (i.e. women, children, elderly, those who lack decision-making capacity) GREB will consider if additional safeguards or justification for

inclusion/excisions may be required to ensure the protection of the rights and welfare of participants;

- 5.1.9 The participant recruitment methods are outlined and copies of the recruitment materials submitted for review;
- 5.1.10 The amount and method of reimbursement, compensation or gifts to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding reimbursement, compensation or gifts to participants includes method, amounts, and schedules to be provided to participants when applicable. Reimbursements, compensation, or gifts to participants may be prorated but should not be contingent on the full completion of participation;
- 5.1.11 The risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk;
- 5.1.12 The risk/benefits to participants are reasonable. GREB should consider the research participants, concerned communities, and other individuals with similar needs relevant to the study;
- 5.1.13 There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;
- 5.1.14 Clear indication to participants is given if the researchers intend to publish their results;
- 5.1.15 Clear indication to participants is given about data security, data storage, and ultimate disposal of the data;
- 5.1.16 Justification for any plans to withhold any information from participants and a method to divulge that information later in the process (i.e. deception studies) is given;
- 5.1.17 Informed consent, to the extent required, is sought from each prospective participant or from the participant's legally authorized representative, in accordance with TCPS 2 and other applicable policies and regulations;

- 5.1.18 The informed consent process is appropriately documented and the informed consent form accurately explains the research and contains the required elements of consent in accordance with TCPS 2 and other applicable policies and regulations;
- 5.1.19 Practices are in place to ensure no prospective or current participant is coerced or unduly influenced to participate in the research;
- 5.1.20 Any additional documentation that GREB or the researchers deem necessary is included in the ethics review.

## **5.2 Additional Criteria**

- 5.2.1 Studies proposing access to or collection of personal information require consideration of additional items to ensure the protection of the privacy of the personal information and to determine whether or not appropriate privacy legislation is adhered to for the full life-cycle of information (i.e. its collection, use, dissemination, retention, and/or disposal);
- 5.2.2 If data linkage is proposed, a description of how the data will be linked is included;
- 5.2.3 If there is likelihood that identifiable data will be created through the data linkage (see TCPS 2, Article 5.7), this possibility is explained;
- 5.2.4 All additional permissions are sought and obtained (e.g., school board, institutional);
- 5.2.5 For research involving Indigenous Participants and/or community based research, the process for engaging the relevant community or justification of why this is not required should be described as outlined in Chapter 9 of the TCPS 2.

## **5.3 Additional Considerations for Collection of Personal Health Information**

- 5.3.1 A description of how Personal Health Information (PHI) will be used in the research and whether or not it will be linked to other information is included;
- 5.3.2 An explanation as to why the research cannot be conducted without the PHI and any foreseeable harms and benefits that may arise from the use of the PHI, and a plan on how to address these issues is necessary;
- 5.3.3 If PHI is collected, procedures to de-identify information prior to the data being released to other researchers must be described.

#### **5.4 Duration of Ethics Clearance**

- 5.4.1 GREB shall review research at periods appropriate to the degree of risk and at least annually.

#### **5.5 Submission requiring HSREB and GREB Clearance**

- 5.5.1 Some research projects combine behavioural measures with neurological/medical measures. Combined protocols will be discussed by both Chairs or designee to determine which Board (GREB or HSREB) should provide ethical oversight; If the site of data collection is at one of the Affiliated Teaching Hospitals it should be submitted to HSREB.

## **6.0 REFERENCES**

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2018

## 7.0 APPENDICES

None.

## 8.0 REVISION HISTORY

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Initial Review - Criteria for GREB Ethical Clearance	v.404.001 2016MAR07	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous documents or policies (using the format of CAREB/N2). .
Initial Review - Criteria for GREB Ethical Clearance	v.404.002 2020	Updates to TCPS 2 references and terminology.