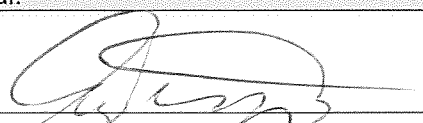
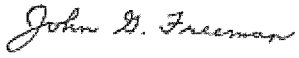
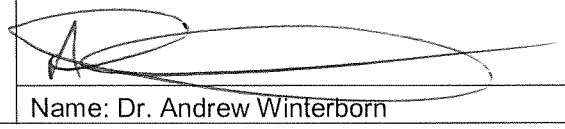
Section 400:	**Review of Research**
Title:	**Criteria for GREB Ethical Clearance**
SOP Code:	**404.001**
Effective Date:	**2016MARCH07**

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor	 Name: Anthony Wright	Date: 2016MAR07
Approval Authority:		
Chair, GREB	 Name: Dr. John Freeman	Date: 2016MAR07
Approval Authority:		
Director, Research Ethics Compliance	 Name: Dr. Andrew Winterborn	Date: 2016MAR07

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 TCPS2 (2014) 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 TCPS2 (2014), 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 using the TRAQ interface 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. GREB will consider logistical and ethical reasons for inclusion/exclusion criteria of vulnerable persons or groups, if applicable;

5.1.8 When some or all of the participants are vulnerable persons or groups (e.g., First Nations, Inuit, Métis People (FNIM), children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination) GREB should consider if they may be at greater risk to coercion or undue influence and whether or not additional safeguards may be required in the research design to ensure the protection of the rights and welfare of these 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 not 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. Where participant risk and benefits are minimal, the importance of the knowledge to society as a whole may be stressed. 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 TCPS2 (2014) and SOP 701.001 Informed Consent Form Requirements and Documentation;

5.1.18 The informed consent form accurately explains the research and contains the required elements of consent (see SOP 701.001 Informed Consent Form Requirements and Documentation);

5.1.19 The informed consent process is appropriately documented in accordance with the relevant regulations (see SOP 701.001 Informed Consent Form Requirements and Documentation);

5.1.20 Practices are in place to ensure no prospective or current participant is coerced or unduly influenced to participate in the research;

5.1.21 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 (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 TCPS2, 2014, Article 5.7), this possibility is explained;

5.2.4 Special permissions are normally required when working with children, the elderly, mentally or physically disabled individuals or prisoners. These permissions may come from school authorities and parents/guardians. They may require institutional clearance;

5.2.5 When conducting research with First Nations, Inuit and Métis Peoples (FNIM), please refer specifically to Chapter 9 of the

TCPS2 (2014). For research involving FNIM participants, the process for engaging the relevant community or an explanation for omission of this step must be described.

5.3 Additional Considerations for Collection of Personal Health Information

5.3.1 A description of how the 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 (acquired at Queen's) with neurological/medical measures (acquired at Queen's or Affiliated Teaching Hospitals);

5.5.2 Combined protocols will be discussed by both Chairs to determine which Board (GREB or HSREB) should review and clear the ethics application;

5.5.3 If the site of data collection is at one of the Affiliated Teaching Hospitals, the ethics application will normally be reviewed and

cleared by HSREB. Please refer to HSREB Standard Operation Procedures for further information.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
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). .