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| | REB Ethical Clearance |
| SOP Code: | 404.002 |
| Effective Date: | 2020DEC14 |

Site Approvals

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| <i>Signature of Responsible Individual:</i> | | |
| <i>Manager , Research Ethics Compliance</i> |  | <i>Date:</i> |
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| <i>Approval Authority:</i> | | |
| <i>Chair, GREB</i> |  | <i>Date:</i> |
| | <i>Name: Dr. Dean Tripp</i> | |
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| <i>Director, Research Ethics Compliance</i> |  | <i>Date:</i> |
| | <i>Name: Dr. Andrew Winterborn</i> | |

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

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

- 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 so Tdaud-3 (opo)-n2 perc; 0 Tc.003 Tw o.03 Tw C

- 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

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 |