

GENERAL RESEARCH ETHICS BOARD STANDARD OPERATING PROCEDURES

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Section 100:	General Administration
Title:	Authority and Purpose
SOP Code:	101.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to:

1. State the organizational authority under which the Queen's University General Research Ethics Board (GREB) is established and empowered;
2. Define the purpose of GREB;
3. State the principles governing GREB to assure that participants are protected based on the TCPS2 (2014) core principles of: (a) respect for persons, (b) concern for welfare, and (c) justice.

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

Queen's University, all GREB members, and all GREB office personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 AUTHORITY

The Principal of Queen's University has invested in the General Research Ethics Board (GREB) the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted by members of Queen's University (TCPS2, 2014, Articles 6.1 and 6.3). GREB primarily has human ethics authority over humanities, social science, science, engineering, and administrative research involving humans, whereas the Health Sciences Research Ethics Board (HSREB) primarily has authority over health sciences, medical, and hospital-affiliated research involving humans. In some circumstances discussion between the GREB and HSREB Chairs is required to determine which Board is best suited to review research submissions. GREB uses the considerations set forth in the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research*

Involving Humans (TCPS 2, 2014) as a minimum standard on which to base decisions and to ensure that decisions are made in accordance with Queen's University policies.

Queen's University maintains an arms-length relationship with GREB. While GREB is accountable to the Principal through the Vice-Principal (Research) of Queen's University for ensuring that correct processes are followed for ethics review, it is independent in its decision making. The administration of Queen's University may not override negative GREB decisions reached on grounds of non-compliance with research ethics. Similarly, GREB may not override Queen's University decisions to not allow certain research within its jurisdiction, even if GREB has found the research ethically acceptable.

When reviewing proposed research, GREB will maintain and follow all written policies and procedures (GREB SOPs) consistent with federal and provincial regulations, good clinical practice, ethics guidelines, and current and emerging best practices.

5.1 Establishment of Organizational Authority

5.1.1 In September 1998, MRC, NSERC, and SSHRC adopted the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS). Institutions and researchers are required to comply with the guidelines to be eligible for support from the three federal granting councils. In November 1998, Dr. Suzanne Fortier, Vice-Principal (Research) at the time, established an Advisory Committee to report on issues related to the implementation of the Tri-Council Policy at Queen's University. The *Report of the Advisory Research Committee (ARC) Ethical Conduct for Research Involving Human Subjects* recommended that the University adopt the Tri-Council Policy Statement to replace the 1973 policy (*The Report of the Advisory Research Committee on the Ethics Review of Research Involving Human Subjects*) and that it support the creation of the General University Research Ethics

Board (GREB) to review all non-health sciences protocols. Queen's Senate approved the recommendations of the ARC in October 1999.

5.2 Reporting and Financial Relationship

- 5.2.1 The Director of Research Ethics Compliance submits an annual report to Queen's University through the Vice Principal (Research);
- 5.2.2 Queen's University is responsible for providing sufficient and ongoing financial and administrative resources to ensure GREB can fulfill its mandate (TCPS2, 2014, Article 6.2).

5.3 Purpose of GREB

- 5.3.1 GREB was established to review all research involving human participants within its established jurisdiction;
- 5.3.2 GREB's purpose is to protect the rights and welfare of human participants participating in research;
- 5.3.3 GREB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection and current and emerging best practices;
- 5.3.4 These regulations and guidelines include, but are not limited to, the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2, 2014), the Freedom of Information and Protection of Privacy Act (FIPPA), Personal Health Information Protection Act (PHIPA), the Personal Information Protection and Electronic Documents Act (PIPEDA), and, where applicable, US Federal Regulations.

5.4 Governing Principles

5.4.1 GREB is guided by the ethical principles regarding all research involving human participants based on the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2, 2014):

- a) Respect for Persons:
 - Recognize the intrinsic value of human beings and the respect and consideration they are due;
 - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- b) Concern for Welfare:
 - Aim to protect the welfare of participants, and, in some circumstances, promote that welfare in view of any foreseeable risks;
 - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation;
 - Ensure that participants are not exposed to unnecessary risks.
- c) Justice:
 - Treat people equitably with equal respect and concern;
 - Afford special attention, as needed, to vulnerable or marginalized people.

5.5 GREB Authority

5.5.1 Queen's University has authorized GREB to approve, reject, propose modifications to, or terminate any proposed or ongoing

research involving human participants conducted under the auspices of Queen's University (TCPS2, 2014, Article 6.3);

5.5.2 GREB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants. Specifically, GREB has the authority to:

- Establish the ethics review processes and provide research ethics oversight to ensure the ethical conduct of the research;
- Grant ethics clearance for, require modifications to, or disapprove any research activity that falls within its jurisdiction;
- Ensure that the researcher has policies and procedures to protect the rights, safety, and welfare of research participants;
- Request, receive, and share any information involving the research that GREB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy;
- Conduct continuing ethical review to protect the rights, welfare, and privacy of research participants;
- Suspend or terminate the ethics clearance for the research;
- Place restrictions on the research;
- Use a joint review process for multi-institutional studies or rely on the review of another qualified REB to avoid duplication of effort;
- Take any actions considered reasonably necessary and consistent with policies and procedures to ensure the protection of the rights, safety, and well-being of participants in research conducted under GREB's jurisdiction.

5.6 Research Subject to US Regulations

5.6.1 GREB shall apply the requirements of the applicable US regulations to the extent that they vary from the protections set out

in the applicable Canadian regulations and guidelines, as specified and maintained by the institution. See SOP 408.001 Research Requiring Federalwide Assurance.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. *Report of the Advisory Committee on Research Ethics Board Function in Faculties outside the Faculty of Health Sciences and Affiliated Hospitals.*
2. *Report of the Advisory Research Committee (ARC) Ethical Conduct for Research Involving Human Subjects* (Approved by the Senate: October 1999; replaces *Report of the Advisory Research Committee on the Ethics Review of Research Involving Human Subjects*, 1973).

8.0 REVISION HISTORY

SOP Title	Version	Updates
Authority and Purpose	v.101.001 2016FEB08	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 100:	General Administration
Title:	Research Activities Requiring GREB Review
SOP Code:	102.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date
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Approval Authority:		
Chair, GREB		Date
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Approval Authority:		
Director, Research Ethics Compliance		Date
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

The purpose of this SOP is to describe research activities that require GREB review and research activities that do not.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

All research involving human participants must be reviewed and ethically cleared by a REB. No intervention or interaction with human participants in research, including recruitment and pilot studies, may begin until a REB has reviewed and ethically cleared the research protocol, consent documents, and recruitment materials.

5.1 Research that Requires GREB Review

5.1.1 The following activities require review and ethical clearance by the GREB before the research commences:

- a) All research activities that fall under the definition of research in the TCPS2 (2014) involving human participants in the humanities, social sciences, sciences, and engineering disciplines and university administration. Research is defined in the TCPS2 (2014) as: “An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.”

5.2 GREB to Decide on Research Exemptions

- 5.2.1 Some exemptions of ethics review are set out in specific articles in the TCPS2 (2014). However, the GREB has created some additional guidelines to clarify its position on certain articles.
- 5.2.2 Under TCPS2 (2014), Article 2.1 (Applications) states: "When in doubt about the applicability of this Policy to a particular research project, the researcher shall seek the opinion of the GREB. The GREB makes the final decision on exemption from research ethics review."

5.3 Research that is Frequently Exempted from GREB Review

- 5.3.1 Based on Article 2.2 of the TCPS2 (2014), research that relies exclusively on publicly available information may not require GREB review when:
 - a) The information is legally accessible to the public and appropriately protected by law;
 - b) The information is publicly accessible, and there is no reasonable expectation of privacy;
 - c) However, internet chat rooms and self-help groups with restricted membership access are **not exempt** from ethics review (see Research Involving Digital Data Collection Guidelines at <http://www.queensu.ca/urs/guidelines-greb>).
- 5.3.2 Based on Article 2.3 of the TCPS2 (2014), GREB review may not be required for research involving the observation of people in public places where:
 - a) It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
 - b) Individuals or groups targeted for observation have no reasonable expectation of privacy; and

- c) Any dissemination of research results does not allow for identification of specific individuals.

5.3.3 Based on Article 2.4 of the TCPS2 (2014), research that relies exclusively on secondary use of anonymous information may not require ethics review so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. Articles 5.5A and 5.5B limit the use of Article 2.4;

5.4 Activities that May not Require GREB Review

- 5.4.1 Activities outside the scope of research subject to GREB review may still raise ethical issues that would benefit from careful consideration by GREB or a body capable of providing some independent guidance, other than GREB;
- 5.4.2 Although some exemptions are described in specific articles of the TCPS2 (2014), GREB has created guidelines to clarify the scope of these exemptions. For example, GREB has developed guidelines for Article 2.5 to clarify GREB's expectations (i.e., Course-Based Research, and Quality Assurance and Quality Improvement (QA/QI) activities. They can be found on GREB's Guidelines webpage at <http://www.queensu.ca/urs/guidelines-greb>);
- 5.4.3 Based on Article 2.5 of the TCPS2 (2014), quality assurance and quality improvement (QA/QI) studies, program evaluation activities, performance reviews, and testing within normal educational requirements, when used exclusively for assessment, management, or improvement purposes, do not constitute research for the purposes of this SOP, and may not fall within the scope of GREB review. GREB has developed policies regarding Article 2.5, namely:
 - a) If an instructor submits a course-based application for a pedagogical research assignment that meets certain criteria,

GREB will authorize the instructor to manage the assignment on GREB's behalf (see Student Course-based Research Assignment Guidelines at

<http://www.queensu.ca/urs/sites/webpublish.queensu.ca.urswww/files/files/Student%20Course-Based%20Research%20Assignments.pdf>);

- b) Some QA/QI research activities are exempt from ethics review provided the projects meet the criteria in a decision-making chart (see Quality Assurance/ Quality Improvement Guidelines at

<http://www.queensu.ca/urs/sites/webpublish.queensu.ca.urswww/files/files/GREBQAQIGuidelines0322013final.pdf>);

- 5.4.4 Based on Article 2.6 of the TCPS2 (2014), creative practice activities, in and of themselves, do not require GREB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to GREB review;

6.0 REFERENCES

See References.

7.0 APPENDICES

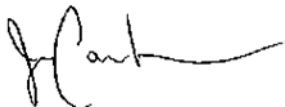

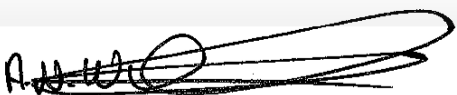
None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Research Activities Requiring GREB Review	v.102.001 2016FEB08	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).

Section 100:	General Administration
Title:	HSREB Training and Education
SOP Code:	103.002
Effective Date:	2020DEC14

Site Approvals

Signature of Responsible Individual:		
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Approval Authority:		
Chair, HSREB		Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		Date
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the training and education requirements for HSREB members, HSREB Office Personnel and HSREB Researchers.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members, HSREB Office Personnel and HSREB Researchers are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

HSREB members, HSREB Office Personnel, HSREB Researchers, and others charged with the responsibility for reviewing, granting ethical clearance, and overseeing human participant research should be well-versed in the regulations, guidelines, policies, and ethical principles applicable to human participant research. The HSREB chair in collaboration with HSREB Office Personnel may advise Queen's University and Affiliated Teaching Hospitals on policies and procedures related to the ethical conduct of research involving human participants. Adequate training and education in these areas is critical for the HSREB to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner.

5.1 Training and Education – HSREB Members

- 5.1.1 The HSREB Chair or designee in combination with HSREB Office Personnel, will provide new HSREB members with a general overview of the policies and procedures pertinent to HSREB meeting functions and HSREB member expectations, as well as an orientation to the principles and guidelines for research ethics;
- 5.1.2 The HSREB Chair or designee, in conjunction with HSREB Office Personnel, will assess educational and training needs of HSREB members to identify and address any gaps in knowledge, skills or competencies required to fulfil their duties;
- 5.1.3 HSREB performance feedback will be provided on an ongoing basis by the HSREB Chair or designee to HSREB Office Personnel as appropriate;
- 5.1.4 New HSREB members will receive an orientation before beginning their formal duties;
- 5.1.5 All new HSREB members will be required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE).
- 5.1.6 HSREB members are expected to participate in the orientation process which may include, but is not limited to:
 - Background on the HSREB (e.g., Terms of Reference, governance structure, annual reports),
 - Policies and Procedures (e.g., relevant SOPs and associated forms, consent form template, consent form checklist),
 - Ethics system training,
 - Member information (e.g., meeting schedule, membership list, information and guidelines for members, reviewer guide),
 - Regulatory and guidance documents,

- Other member-specific information (e.g., copy of signed Confidentiality Agreement and Conflict of Interest Disclosure Form, Membership Appointment Letter),
 - Resource information (e.g., list of training and education references, relevant articles, etc.);
- 5.1.7 As part of their orientation, new HSREB members will be offered the opportunity to observe at least one HSREB meeting prior to commencing their HSREB member duties;
- 5.1.8 HSREB members are encouraged to attend conferences and other educational sessions pertaining to human participant research protection, such as the Canadian Association of Research Ethics Board (CAREB) annual general meeting and CAREB regional meetings. The HSREB office will support such activities to the extent possible and as appropriate to the responsibilities of HSREB members and HSREB Office Personnel. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);
- 5.1.9 Ongoing ethics education in areas germane to the HSREB members' responsibilities may be provided at HSREB meetings;
- 5.1.10 All HSREB members and any relevant Office Personnel will be invited to attend the annual Spring Retreat, at which current ethical issues are discussed in depth. The recommendations elicited from these retreats are used to guide the development of HSREB policy and procedures;
- 5.1.11 Applicable new or revised policies and SOPs will be disseminated to the new HSREB members;
- 5.1.12 HSREB members are encouraged to engage in self-directed learning in research ethics and in the conduct of research to enhance their ability to fulfill their responsibilities.

5.2 Training and Education – HSREB Office Personnel

- 5.2.1 The Manager, Research Ethics Compliance or designee, will provide new HSREB Office Personnel with an overall orientation to the HSREB, including a general overview of the policies and procedures pertinent to their role in support of the HSREB;
- 5.2.2 The Manager, Research Ethics Compliance or designee, will assess educational and training needs of HSREB Office Personnel to identify and address any gaps in knowledge, skills or competencies required to fulfil their duties;
- 5.2.3 New HSREB Office Personnel will receive training on the HSREB SOPs and will be expected to be knowledgeable and compliant with the SOPs;

- 5.2.4 New HSREB Office Personnel are required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE) and are encouraged to complete additional and ongoing relevant education and training in research ethics and in the conduct of research;
- 5.2.5 HSREB Office Personnel are encouraged to attend conferences and educational sessions pertaining to human participant research protection, such as the CAREB annual general meeting and CAREB regional meetings. The HSREB office will support such activities to the extent possible and as appropriate to the responsibilities of HSREB members and HSREB Office Personnel. Conference attendance is based on availability of funding and other practical considerations (e.g., workload, staffing, conference location);
- 5.2.6 New or revised policies and SOPs will be disseminated to the HSREB Office Personnel;
- 5.2.7 HSREB Office Personnel are encouraged to engage in self-directed learning to enhance their ability to fulfill their responsibilities.

5.3 Training and Education – Researchers

- 5.3.1 All project team members performing significant study-related duties, including those who have access to study data, are required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE). This policy applies to all faculty, librarians, archivists, post-doctoral fellows, medical residents, graduate and undergraduate students, staff and external applicants. The Office of Research Ethics Compliance will accept Good Clinical Practice (GCP) and the CITI Biomedical Ethics Tutorial as equivalent ethics training modules in lieu of the CORE tutorial. The Office of Research Ethics Compliance may accept other ethics training certifications in lieu of the CORE tutorial; however, this is at the discretion of the Office of Research Ethics Compliance. Proof of equivalent ethics training must be attached to the ethics application in TRAQ;
- 5.3.2 All affiliated hospital-based researchers that will be performing significant study-related duties for clinical trials should be trained in Good Clinical Practice (GCP) as per current affiliated hospital policies (Kingston Health Sciences Centre (KHSC) and Providence Care Centre (PCC) in lieu of CORE training;

- 5.3.3 Proof of ethics training must be included with ethics submissions for all project team members performing significant-study related duties;
- 5.3.4 Researchers are also encouraged to complete additional and ongoing relevant education and training in research ethics and the conduct of research.

5.4 Documentation of Ethics Training for HSREB Members and HSREB Office Personnel

- 5.4.1 The Office of Research Ethics Compliance will retain copies of CVs for HSREB members and HSREB Office Personnel;
- 5.4.2 HSREB members and HSREB Office Personnel will record their relevant training and education and provide copies of their certificates of completion. Training records will be kept on file in the Office of Research Ethics Compliance;
- 5.4.3 HSREB members and HSREB Office Personnel are encouraged to retain copies of agendas of relevant workshops, seminars and conferences attended;
- 5.4.4 HSREB agendas and minutes will record the distribution of any educational materials presented at the HSREB meetings.

5.5 Documentation of Ethics Training for HSREB Researchers

- 5.5.1 Proof of ethics training must be attached to the ethics application for all applicants performing significant study-related duties;
- 5.5.2 In some circumstances an exemption may be granted for the completion of ethics training. In these cases the exemption from the Office of Research Ethics Compliance must be attached to the ethics application in TRAQ.

6.0 REFERENCES

See References.

7.0 APPENDICIES

1. SOP Training Log

8.0 REVISION HISTORY

SOP Title	Version	Updates
Training and Education	v.103.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.
Training and Education	v.103.002 2020	<ol style="list-style-type: none"> 1. Section 5.1 Training and Education – Researchers added and Section 5.5 Documentation of Ethics Training for HSREB Researchers added. 2. Updates made to for new policy to require CORE training for all applicants as of Dec 2, 2019. 3. Minor updates to terminology.

Section 100:	General Administration
Title:	Management of GREB Office Personnel
SOP Code:	104.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the overall management of GREB office personnel.

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

The GREB Chair or designee and GREB office personnel are responsible for ensuring that the requirements of this SOP are met. Queen's University is responsible for providing sufficient resources to adequately support the functions of the GREB.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

GREB office personnel provide consistency, expertise, and administrative support to GREB, and serve as a daily link between GREB and the research community. GREB office personnel are vital to ensuring the efficient and effective administration and enforcement of GREB decisions; thus the highest level of professionalism and integrity is expected.

5.1 Job Descriptions

- 5.1.1 Job descriptions establish the role requirements for GREB office personnel, in accordance with Queen's University policies and procedures;
- 5.1.2 All GREB office personnel will be provided with a copy of their job description and job expectations and given access to all applicable GREB Ethics Guidelines policies and procedures;
- 5.1.3 GREB office personnel are subject to privacy and confidentiality policies of GREB and Queen's University.

5.2 Responsibilities

- 5.2.1 GREB office personnel responsibilities may include:

- Pre-review of submissions and requests to GREB;
- Quality management activities;
- Management of administrative issues involving GREB research ethics oversight as described by applicable GREB policies;
- Implementation of GREB directives; and
- Provision of advice and information to GREB.

5.3 Hiring and Terminating GREB Office Personnel

5.3.1 Queen's University has the responsibility for the recruitment, hiring, continuing review, and termination of GREB office personnel, in accordance with Queen's University policies and procedures.

5.4 Delegation of Authority or Responsibility

5.4.1 The GREB Chair may formally delegate appropriate tasks or responsibilities to GREB office personnel provided the delegated individual has the expertise to carry out the task(s), the task is compliant with GREB SOPs, and the task delegation has been agreed to by both GREB office personnel and applicable Queen's University official(s);

5.4.2 Delegation of tasks by the GREB Chair must be documented in writing, and if applicable, approved by the Director of Research Ethics Compliance (see SOP 106.001: Signatory Authority).

5.5 Performance Evaluations and Documentation

5.5.1 Performance feedback with respect to GREB office personnel will be provided on an ongoing basis by the GREB Chair or designee to the Director of Research Ethics Compliance;

- 5.5.2 Queen's University has the responsibility for conducting formal performance evaluations in accordance with Queen's University's policies and procedures;
- 5.5.3 Queen's University has the responsibility for identifying, documenting, and retaining formal GREB office personnel interactions.

5.6 Periodic Evaluation of GREB Office Human Resource Needs

- 5.6.1 A periodic evaluation of the adequacy of GREB resources will be conducted by the Director of Research Ethics Compliance;
- 5.6.2 The evaluation will assess the extent to which GREB office personnel, equipment, finances, and space are adequate to carry out their function in support of GREB;
- 5.6.3 This assessment takes into consideration the volume, complexity, and types of research projects administered by GREB office personnel and whether or not activities in support of GREB can be completed in a timely manner;
- 5.6.4 The need for additional resources will be discussed by the Director of Research Ethics Compliance in conjunction with the GREB Chair and other Queen's University official(s) as appropriate.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Management of GREB Office Personnel	v.104.001 2016FEB08	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).

Section 100:	General Administration
Title:	Conflicts of Interest (COI): GREB Members and Office Personnel
SOP Code:	105A.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes potential Conflicts of Interest (COI) for GREB members (including the GREB Chair and any ad hoc advisors) and GREB office personnel. It describes the requirements and procedures for disclosure and management of COI.

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 disclosing any real, potential, or perceived COI and for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Conflict of Interest (COI) is defined as: the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another (TCPS2, 2014).

A COI (real, potential, or perceived) may arise when individuals are placed in a situation where their professional, personal, or financial interests conflict with their responsibilities to GREB. The most common type of COI occurs when individuals are directly involved in a research project that has been submitted for GREB review or have a friend/colleague involved in the research. COI may also be an issue if individuals have a financial interest in the research project or a relationship with a funder or sponsor. Such competing interests may influence their professional judgment, objectivity, and independence and can potentially influence the outcome of a GREB decision for personal benefit. A COI may exist even if no unethical or improper act results from the conflict. More information is available in Chapter 7 of TCPS2.

GREB must be perceived to be fair and impartial, immune from pressure by the sponsor, Queen's University, the researchers whose research is being reviewed, or other professional and/or non-professional sources. GREB should identify and manage COI to maintain the confidence and trust of the public, the institution, researchers, and colleagues, and to maintain the independence and integrity of the ethics review.

The standard that guides decisions about determining COI is whether or not an independent observer could reasonably question that the individual's actions or decisions are based on factors other than the rights, welfare, and safety of the participants.

If a COI cannot be avoided, the following procedures are designed to mitigate the conflict:

5.1 Delegated Reviews

- 5.1.1 GREB members are not assigned delegated reviews from their home department;
- 5.1.2 The GREB Chair or designee will assess projects undergoing the delegated review process to determine potential COI;
- 5.1.3 If a review is assigned where there is a COI or perceived COI, the reviewer must contact the GREB Coordinator about this concern;
- 5.1.4 If a COI is identified, the project is assigned to another GREB member.

5.2 Full Board Review

- 5.2.1 For full board reviews, the GREB Chair or designee reviews the agenda prior to the GREB meeting to identify potential COI.
- 5.2.2 When the full board agenda is distributed, GREB members are expected to contact the GREB Coordinator, as soon as possible, about a COI, so that another member can be assigned the file;
- 5.2.3 GREB members are reminded of their obligation to orally disclose/declare any real, potential, or perceived COI at the start of each full board meeting;
- 5.2.4 If a COI is declared, the GREB member may be asked to leave the room during discussions of the research project or may be asked to remain to provide further information about the research project;

- 5.2.5 The COI member must not become involved in the deliberation or the decision;
- 5.2.6 The GREB member's recusal will be recorded in the minutes, and the GREB member will not be counted towards quorum.

5.3 GREB Chair

- 5.3.1 In the event that the GREB Chair declares a COI, the Vice-Chair or alternate GREB member will assume the GREB Chair's responsibilities for the specific project(s).

5.4 GREB Office Personnel

- 5.4.1 At the time of hiring, all GREB office personnel sign a Confidentiality Agreement and Conflict of Interest Disclosure Form as a condition of their employment with Queen's University agreeing to abide by the COI and confidentiality policies of Queen's University. GREB office personnel must also comply with GREB COI SOPs;
- 5.4.2 All GREB office personnel are expected to disclose any conflicts that arise. Any GREB office personnel whose job status or compensation is impacted by research that is reviewed by the GREB must excuse themselves when such research is reviewed (e.g., GREB office personnel work with a researcher who has submitted a research application; GREB office personnel have a vested interest in the findings of a research project);
- 5.4.3 Any disclosure of a COI by GREB office personnel should be referred to the Director of Research Ethics Compliance for the development of a management plan;
- 5.4.4 If GREB office personnel are unclear as to whether or not a COI exists, they must contact the GREB Chair or designee or the Director of Research Ethics Compliance to seek clarification. The

Director of Research Ethics Compliance shall determine whether the circumstances should be defined as a COI.

5.5 External Ad Hoc Advisors

- 5.5.1 At the GREB Chair's or designee's discretion, individuals with competence in special areas to assist in a review may be invited to the GREB meeting for their expertise;
- 5.5.2 All ad hoc advisors must sign a Confidentiality Agreement and Conflict of Interest Disclosure Form prior to commencement of their consultation, disclosing any COI to the GREB Chair or designee;
- 5.5.3 Any disclosure of a COI by an ad hoc advisor should be referred to the GREB Chair or designee for the development of a management plan, as applicable;
- 5.5.4 If ad hoc advisors are unclear as to whether or not a COI exists, they must contact the GREB Chair or designee to seek clarification. The GREB Chair or designee will determine whether the circumstances should be defined as a COI.

5.6 Documentation

- 5.6.1 GREB members sign a Confidentiality Agreement and Conflict of Interest Disclosure Form when they first join GREB;
- 5.6.2 All GREB members are reminded of their Confidentiality Agreement and asked about any COI at each GREB meeting;
- 5.6.3 All visitors and ad hoc advisors sign a Confidentiality Agreement and Conflict of Interest Disclosure Form and agree to abide by these policies;
- 5.6.4 The signed Confidentiality Agreements and Conflict of Interest Disclosure Forms will be filed in the Office of Research Ethics;
- 5.6.5 GREB minutes will record:
 - a) Any COI that is declared on any of the projects under review,

- b) The management plan to address the conflict if applicable,
- c) The recusal of a GREB member.

5.6.6 The GREB management plan for Research COI declarations will be documented in the appropriate research files.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Confidentiality Agreement – GREB Members
2. Confidentiality Agreement – GREB Staff Members
3. Confidentiality Agreement – GREB Visitors
4. Confidentiality Agreement – GREB Ad Hoc Advisors
5. Confidentiality Agreement – GREB Alternate Members

8.0 REVISION HISTORY

SOP Title	Version	Updates
Conflict of Interest: GREB Members and Office Personnel	v.105.001A 2016FEB08	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).

Section 100:	General Administration
Title:	Conflicts of Interest (COI): Researchers
SOP Code:	105.001B
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes potential Conflicts of Interest (COI) for researchers and research staff engaged in human participant research, and the requirements and procedures for disclosure and management of such COI.

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

Researchers are responsible for disclosing any real, potential, or perceived COI to GREB.

GREB is responsible for determining whether or not the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Conflict of Interest (COI) is defined as: the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another (TCPS2, 2014).

A COI (real, potential, or perceived) may arise when individuals are placed in a situation where their professional, personal, or financial interests conflict with their responsibilities to GREB. The most common type of COI occurs when individuals are directly involved in a research project that has been submitted for GREB review or have a friend/colleague involved in the research. COI may also be an issue if individuals have a financial interest in the research project or a relationship with a funder or sponsor. Such competing interests may influence their professional judgment, objectivity, and independence and can potentially influence the outcome of a GREB decision for personal benefit. A COI may exist even if no unethical or improper act results from the conflict. More information is available in Chapter 7 of TCPS2.

Researchers and research staff should identify and manage COI to maintain the public confidence and trust, and the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict.

This SOP is not intended to prohibit researcher relationships with companies; however, GREB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI.

GREB must be perceived to be fair and impartial, immune from pressure by the sponsor, Queen's University, the researchers whose research is being reviewed, or other professional and/or non-professional sources. GREB should identify and manage COI to maintain the confidence and trust of the public, the institution, researchers, and colleagues, and to maintain the independence and integrity of the ethics review.

The standard that guides decisions about determining COI is whether or not an independent observer could reasonably question that the individual's actions or decisions are based on factors other than the rights, welfare, and safety of the participants.

5.1 Researcher Disclosure of Conflicts of Interest

- 5.1.1 Researchers submitting research applications to the GREB are required to declare any COI including those of any researcher or sub/co-researcher(s), research staff, and their immediate families;
- 5.1.2 Researchers are additionally required to provide information on the budget, as applicable, when submitting a research application;
- 5.1.3 Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict;
- 5.1.4 Researchers shall disclose any conflicts to GREB at the following times:
 - a) With the initial GREB application,
 - b) At each renewal review of the project,

- c) Whenever a COI arises, such as changes in responsibilities or financial circumstances;
- 5.1.5 Researchers shall cooperate with GREB and other university official(s) involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of GREB and with any other Queen's policies. Policies to eliminate and/or to manage the conflict may include, but are not limited to, the QUFA-Queen's Collective Agreement (August 21, 2015 - April 30, 2019; Appendix 1), Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty; Appendix 2), Human Resources Conflict of Interest and Conflict of Commitment Policy (Appendix 3), and the Monieson Centre - Policy on Authorship and Co-authorship December 2010 (Appendix 4);
- 5.1.6 Researchers shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

5.2 GREB Review of Researcher Conflict of Interest

- 5.2.1 GREB will review each application for disclosure of COI;
- 5.2.2 If a researcher indicates on the GREB application that a conflict exists, GREB will determine whether or not the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research;
- 5.2.3 GREB review shall focus on those aspects of the COI that may reasonably affect human participant protection; the steps taken should be context-based and commensurate with the risks as per Chapter 7 of TCPS2;
- 5.2.4 In determining the appropriate action, GREB may take into consideration information presented by the researcher such as:
 - a) The nature of the research,
 - b) The magnitude of the interest or the degree to which the conflict is related to the research,
 - c) The extent to which the interest could affect the research,

- d) Whether or not a specific individual is unique in clinical or scientific qualifications to conduct the research,
- e) The degree of risk to the human participants involved in the research that is inherent in the research, and/or
- f) The management plan for the COI already developed by the researcher;

5.2.5 GREB may grant ethical clearance for the research; however, it may require that the researcher submit a plan to GREB to manage the COI, which may include changes at the researcher's or sponsor's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:

- a) Divestiture or termination of relevant economic interests,
- b) Mandated researcher recusal from research,
- c) Modification or limitation of the participation of the researcher in all or in a portion of the research,
- d) In cases involving equity, imposition of a bar on insider trading or requirement that securities be transferred to an independent financial manager or blind trust, or limitations on the timing of sales or distributions,
- e) Monitoring of research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting [versus withholding data]),
- f) Monitoring of the consent process, and/or
- g) Disclosure of the conflict to organizational committees, research participants, and journals;

5.4.6 GREB has the final authority to determine whether or not a COI has been eliminated or managed appropriately;

5.4.7 Any COI management plan will be documented in the research ethic file. Any discussions at the GREB meeting regarding the COI and the management plan will be documented in the GREB meeting minutes;

- 5.4.8 After review by GREB and input by appropriate Queen's University official(s), if applicable, GREB may reject research that involves a COI that cannot be appropriately managed.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Collective Agreement (Faculty, Librarians and Archivists) Between Queen's University Faculty Association (QUFA) and Queen's University at Kingston (August 21, 2015 - April 30, 2019):
<http://www.queensu.ca/facultyrelations/sites/webpublish.queensu.ca/files/files/CA%202015-19%20with%20changes%20marked%20and%20compensation%20added.pdf>
2. Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty):
<http://www.queensu.ca/secretariat/policies/senateandtrustees/conflict.html>
3. Human Resources Conflict of Interest and Conflict of Commitment Policy:
<http://www.queensu.ca/humanresources/policies/workplaceissues/conflictofinterest.html>
4. The Monieson Centre - Policy on Authorship and Co-authorship December 2010:
[http://business.queensu.ca/ConversionDocs/Monieson/Policy_on_Authors hip_and Co-authorship December 2010.pdf](http://business.queensu.ca/ConversionDocs/Monieson/Policy_on_Authors hip_and_Co-authorship_December_2010.pdf)

8.0 REVISION HISTORY

SOP Title	Version	Updates
Conflict of Interest: Researcher	v.105.001B 2016FEB08	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).

Section 100:	General Administration
Title:	Conflict of Interest: Queen's University
SOP Code:	105.001C
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes potential Conflicts of Interest (COI) in the relationship between Queen's University in establishing GREB and GREB itself, and the requirements and procedures for disclosure and management of potential COI within this relationship.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Conflict of Interest (COI) is defined as: the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another (TCPS2, 2014).

Queen's University's and other applicable COI policies (see SOP 105A, Conflicts of Interest (COI): GREB Members and Office Personnel; SOP 105B, Conflicts of Interest (COI): Researchers) should address the roles, responsibilities, and process for identifying, eliminating, minimizing, or otherwise managing COI relevant to research, including disclosure to GREB. Management of COI includes, but is not limited to, prevention, evaluation, disclosure, and application of appropriate remedies as defined by Queen's University.

GREB must be perceived to be fair and impartial, immune from pressure by the sponsor, Queen's University, the researchers whose research is being reviewed, or other professional and/or non-professional sources. GREB should identify and manage COI to maintain the confidence and trust of the public, the institution, researchers, and colleagues, and to maintain the independence and integrity of the ethics review.

The standard that guides decisions about determining COI is whether or not an independent observer could reasonably question that the individual's actions or

decisions are based on factors other than the rights, welfare, and safety of the participants.

5.1 Disclosure of COI

- 5.1.1 All Queen's University employees should be familiar with the Queen's University's and other applicable COI policies (see SOP 105A, Conflicts of Interest (COI): GREB Members and Office Personnel; SOP 105B, Conflicts of Interest (COI): Researchers);
- 5.1.2 Prior to engaging in any of the professional activities outlined in the COI policies and SOPs, employees should seek the approval of the Director of Research Ethics Compliance to ensure that no conflict exists in doing so;
- 5.1.3 GREB members shall be apprised of Queen's University's organizational structure with emphasis placed on the independent nature of the relationship between GREB and Queen's University, as outlined in SOP 101, Authority and Purpose. The actions of GREB Members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;
- 5.1.4 GREB meetings are closed to employees of Queen's University unless they are GREB members, GREB office personnel, authorized observers, or visitors invited by GREB to provide information. These designated individuals can attend GREB meetings only after signed confidentiality agreements are in place;
- 5.1.5 Queen's University senior administrators shall not serve as GREB members nor observe GREB meetings when their presence may influence GREB deliberations. The mere presence of non-voting institutional senior administrator(s) at GREB meetings may be a source of real, potential, or perceived COI, and may undermine the

independence of the GREB by unduly influencing deliberations and decisions;

- 5.1.6 Queen's University and GREB policies and procedures will be made publicly available to all members of the research enterprise, including participants, researchers, administrators, and sponsors, on the Queen's University Research Ethics website.

5.2 Management of COI

- 5.2.1 The GREB Chair or designee must be notified if a Queen's University COI relating to GREB is declared or discovered;
- 5.2.2 The GREB Chair or designee must be notified immediately if any Queen's University employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment;
- 5.2.3 The GREB Chair or designee and/or Director of Research Ethics Compliance will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human participant protection;
- 5.2.4 The GREB Chair or designee may require a plan to manage the COI, which may include actions to eliminate or mitigate the conflict. Required actions may include, but are not limited to:
- Divestiture or termination of relevant economic interest,
 - Recusal of GREB office personnel whose job status or compensation is impacted by research that is reviewed by GREB,
 - If Queen's University staff members are involved, provision of information to the appropriate responsible Queen's University management personnel to develop and implement a plan for remediation,

- If the GREB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on GREB, the GREB Chair or designee will bring these concerns to the Director of Research Ethics Compliance for determination of the appropriate course of action;

5.2.5 In the event that the GREB Chair or designee cannot bring the matter to the appropriate Queen's university official(s) because of an emergent situation or competing COI with Queen's University, the GREB Chair or designee may escalate the issue to the Board authority.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Conflict of Interest: Queen's University	v.105.001C 2015FEB08	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).

Section 100:	General Administration
Title:	Standard Operating Procedures Maintenance
SOP Code:	106.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the processes for establishing and maintaining written SOPs. The purpose of having written SOPs is to promote quality and consistency in the ethics review process; ensure compliance with the principles, guidelines, and regulations applicable to the ethics review and oversight of research involving humans; and facilitate training of new personnel.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Written SOPs provide the framework to promote ethical standards in the review, oversight, and conduct of research involving human participants. SOPs describe the processes that must be followed and documented to ensure that the rights and welfare of human participants of such research are overseen and protected in a uniform manner.

5.1 Development, Review, Revision and Approval of Policies and Procedures

- 5.1.1 The Ethics Compliance Advisor will review the SOPs annually. Applicable SOP(s) will be reviewed more frequently if changes to regulations, guidelines, or standard practice warrant revisions or the creation of new SOP(s). SOPs may be revised for reasons including, but not limited to: changes to regulations or guidelines, new policies, or changes to GREB or administrative practices;
- 5.1.2 The Ethics Compliance Advisor will make the necessary modifications to existing SOP(s) or draft new SOP(s). SOPs are controlled documents. New drafts will be indicated by the addition of “DRAFT version date” and removal of the previous “Final Version Date”;

- 5.1.3 The revised SOP(s) will be circulated to GREB office personnel and GREB Chair or designee, as well as GREB members (as appropriate) for review. Comments will be incorporated into a new version with an updated version date;
- 5.1.4 Once the SOP content is approved, the draft version date will be removed and the date of the approved version will be entered as the “Final Version Date.” The history of revisions will be recorded in the ‘SOP History’ section of each SOP;
- 5.1.5 Signatures on the SOP as determined by Queen’s University policy, will denote SOP approval. A new final version of the SOP supersedes any previous versions.

5.2 Distribution and Communication

- 5.2.1 New or revised SOPs and associated guidance documents will be communicated and disseminated to all applicable individuals;
- 5.2.2 The SOPs will be available to researchers, researcher sites, sponsors, and regulatory authorities as required;
- 5.2.3 The Ethics Compliance Advisor will inform GREB members and GREB office personnel of any new or revised policy and/or relevant procedure, as applicable;
- 5.2.4 Each new GREB member is expected to review the applicable policies and procedures prior to undertaking responsibilities as a GREB member;
- 5.2.5 Each new GREB office personnel must review the applicable policies and procedures prior to undertaking responsibilities with the GREB office.

5.3 Forms, Memos, and Guidance Documents

- 5.3.1 Forms, such as checklists and worksheets, may be developed to facilitate compliance with the SOPs and ensure that policies are

integrated into daily operations. Forms may be either controlled or non-controlled;

5.3.2 Memos and guidance documents may be developed to provide guidance for the interpretation and implementation of the SOP;

5.3.3 Memos and guidance documents will be made available to researchers and researcher sites as applicable;

5.3.4 The Ethics Compliance Advisor will evaluate the need for new or revised forms, memos, or guidance documents.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. SOP Template

8.0 REVISION HISTORY

SOP Title	Version	Updates
Standard Operating Procedures Maintenance	v.106.001 2016FEB08	Original: This SOP was developed based on the CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to reflect institutional policies.

Section 100:	General Administration
Title:	General Research Ethics Board (GREB) Course-Based Research
SOP Code:	107.001
Effective Date:	2016AUG16

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date:
	Name: Jennifer Couture	
Approval Authority:		
Chair, GREB		Date:
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date:
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to outline the criteria for determining categories of course-based research assignments and specify who is responsible for implementing and overseeing the course-based ethics 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, GREB office personnel, and course-based research instructors are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Chapter 6 of the TCPS2 (2014) encourages establishing written procedures and criteria for determining the categories of research that may be eligible for different types of ethical review. In some instances, course based research may be eligible for instructor oversight pending GREB clearance of an Instructor Course-Based Research Assignment Application form. All research projects involving human participants that **do not** meet the criteria for student course-based research assignments must comply with the standard GREB application process.

5.1 Criteria for Instructor Review

5.1.1 The following criteria must be met in order for the research project to be eligible for instructor oversight:

- The research is conducted solely for educational and/or student assessment purposes,
- Risks to both researcher(s) and participant(s) must be minimal (i.e., no greater than risks encountered in everyday life),
- Researchers should only recruit enough participants necessary to achieve the educational objectives of the assignment,
- There is no reasonable expectation of privacy attached to the research data that will be collected,

- Research results will not be disseminated outside of the classroom environment or associated controlled settings, or for online courses, outside the online course's password protected domain,
- The data obtained from student course-based research projects **cannot** later be used for research projects involving dissemination outside of the classroom environment as secondary use of data.

5.2 Research Project Criteria

5.2.1 The following research project criteria must be met in order for the research project to be eligible for instructor oversight:

- Student projects will not involve deception,
- Student project will not provide incentives for participation,
- All participants will be capable of giving free and informed consent,
- Student projects will be minimal risk only, and not involve risks greater than those encountered in participants' everyday life,
- Student projects will not involve physically invasive contact with participants,
- Participants will not be drawn from populations that may require special considerations, as outlined in the TCPS2 (<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/#toc01-1a/>). These populations may include individuals who identify as First Nations, Inuit, or Metis; children; prisoners; elderly; those participants who have experienced a mental illness; and those with diminished capacity for self-determination.

5.3 GREB Course-Based Research Application Process

- 5.3.1 Instructors must submit an Instructor's GREB Course-Based Research Assignment Application form using TRAQ;
- 5.3.2 All supplemental documentation must be included in the application as applicable (e.g. course outline, handouts pertaining to the assignment, sample LOIs, CFs, and recruitment scripts);
- 5.3.3 Once GREB clearance has been obtained for the Instructor's GREB Course-Based Research Assignment Application, students may complete the GREB Short Application Form for Course-Based Research (Appendix 1), which is posted on the GREB website; however this form is not mandatory;
- 5.3.4 The course instructor is responsible for securely retaining any documentation and/or forms related to course-based research for a minimum of **five years**;
- 5.3.5 Any changes to the initially cleared research must be submitted on a General Research Ethics Board Request for the Amendment of Approved Studies form in TRAQ;
- 5.3.6 All course-based research may be subject to GREB audit.

5.4 Types of GREB Course-Based Research

5.4.1 Individualized course-based research assignments:

- Involves a research assignment provided by the course instructor with specific objectives, where students must follow clearly specified guidelines. Student course-based research assignments may vary among students but they may not go beyond the Instructor and research criteria as outlined in section 5.1 and 5.2 of this SOP;

5.4.2 Common course assignments/Laboratories

- Involves assignments in which all students are participating in or conducting a common research project. Typically, all students are addressing the same research question. The course

instructor is expected to make the common task voluntary and anonymous (especially if participants are the students from the course). If instructors wish to use this type of laboratory project for their own research, they must get a separate ethics clearance.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. GREB Short Application Form for Course-Based Research

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Course Based Research	v.107.001 2016AUG16	Original

Section 100:	General Administration
Title:	General Research Ethics Board (GREB) Undergraduate Thesis Research
SOP Code:	108.001
Effective Date:	2016AUG16

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date:
	Name: Jennifer Couture	
Approval Authority:		
Chair, GREB		Date:
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date:
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to outline the criteria for determining categories of undergraduate research theses and specify who is responsible for implementing and overseeing the these undergraduate theses.

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, GREB office personnel, and undergraduate thesis supervisors are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Chapter 6 of the TCPS2 (2014) encourages establishing written procedures and criteria for determining the categories of research that may be eligible for different types of ethical review. In some instances, undergraduate thesis research may be eligible for Departmental Review, subject to auditing by GREB. All research projects involving human participants that **do not** meet the criteria outlined in this SOP 108 Student Undergraduate Thesis Research must comply with the standard GREB application process.

5.1 Undergraduate Thesis Research covered under Supervisor's Ethics Clearance

- 5.1.1 If a student's undergraduate research project is based on the supervisor's research project that has already been granted ethics clearance, AND there are **no changes** from the cleared research activities and associated documentation, the student should be added to the research project team through the submission of a General Research Ethics Board Request for the Amendment of Approved Studies form in TRAQ. The Course on Research Ethics (CORE) certificate of the student must be attached to the amendment request;
- 5.1.2 If a student's research project is based on the supervisor's research project that has already been granted ethics clearance, AND **there are minimal departures** from the initially cleared research

activities and associated documentation, these departures should be outlined through the submission of a General Research Ethics Board Request for the Amendment of Approved Studies form in TRAQ. In addition, the student should be added to the research project team on this Event Form in TRAQ. The Course on Research Ethics (CORE) certificate of the student must be attached to the amendment request;

5.2 Undergraduate Thesis Research Review at the Departmental Level, subject to GREB Audit

5.2.1 The following research project criteria must be met for the undergraduate thesis research to be eligible for Departmental oversight, and subject to GREB audit:

- All participants will be capable of giving free and informed consent,
- Risks to both researcher(s) and participant(s) must be minimal (i.e., no greater than risks encountered in everyday life),
- Undergraduate thesis research will not involve deception,
- Undergraduate thesis research will not involve physically invasive contact with participants,
- Participants will not be drawn from populations that may require special considerations, as outlined in the TCPS2 (<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/#toc01-1a/>). These populations may include individuals who identify as First Nations, Inuit, or Metis; children; prisoners; elderly; those participants who have experienced a mental illness; and those with diminished capacity for self-determination.

5.3 Departmental Review Process Subject to GREB Audit

- 5.3.1 Undergraduate thesis research that meet the criteria outlined in this SOP may be reviewed at the departmental level, and will be subject to GREB audit;
- 5.3.2 Students are required to complete the full GREB application form in TRAQ for all undergraduate thesis research;
- 5.3.3 All student researchers must complete the Course on Research Ethics (CORE) and ensure copies of CORE certificates are included with the application;
- 5.3.4 All student researchers must attach proof in their GREB application, in the form of an email or letter, that their supervisor has reviewed the ethics application;
- 5.3.5 Once a student application for an undergraduate thesis has been submitted through TRAQ, it will be directed to the Unit REB in TRAQ;
- 5.3.6 Undergraduate thesis research will be reviewed by a minimum of two departmental reviewers and the Unit REB Chair or designee (e.g., two instructors and Chair of Unit REB);
- 5.3.7 Any undergraduate thesis research that does not meet the criteria outlined in this SOP, as identified during the departmental review, will be forwarded to GREB for full review;
- 5.3.8 Once undergraduate thesis research projects are cleared at the departmental level, they will be forwarded to GREB for audit;
- 5.3.9 Audit findings will be communicated to all applicable departmental instructors, supervisors, and Unit REB reviewers;
- 5.3.10 Any undergraduate thesis research projects identified during an audit that do not meet the criteria outlined in this SOP may be forwarded to GREB for full or delegated review, as applicable;
- 5.3.11 All data and documentation associated with undergraduate thesis research must be securely retained by the instructor or delegated designee for a minimum of five years.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Student Thesis Research	v.108.001 2016AUG16	Original

Section 200:	GREB Organization
Title:	Composition of GREB
SOP Code:	201.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the membership composition requirements of the General Research Ethics Board (GREB).

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.

The GREB Chair and the Director of Research Ethics Compliance are responsible for ensuring that the composition of GREB meets the applicable regulatory requirements.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Individual members of GREB must be qualified through training, experience, and expertise to ascertain the acceptability of proposed research in terms of ethical principles and applicable regulations, guidelines, and standards pertaining to human participant protection.

To promote complete and adequate review of the type of research commonly reviewed by GREB, GREB must include appropriate diversity; therefore, selection of members must include a consideration of professional expertise (including both scientific and non-scientific) to assess the research submitted for review. Additional important considerations are: race, gender, cultural background, research experience, institutional affiliation, and sensitivity to the myriad ethical issues faced by Faculties, departments, and schools served by GREB.

5.1 Selection of GREB Members

5.1.1 In selection of GREB members, equal consideration shall be given to qualified persons regardless of gender.

5.1.2 GREB will make every effort to include cultural and ethnic minorities to represent the population from which research

participants are recruited, within the scope of available expertise needed to conduct GREB's functions;

5.1.3 GREB membership will not consist entirely of members of one discipline;

5.1.4 GREB members will be selected based on the needs of GREB as outlined below and per applicable regulations, guidelines, and standards.

5.2 Composition of GREB

5.2.1 The membership of the GREB will be in compliance with the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2, 2014) and, when applicable, the US Code of Federal Regulations;

5.2.2 The GREB Chair and the Director of Research Ethics Compliance need to monitor GREB membership composition and size based on the types of applications GREB receives and reviews, the number of reviews, and the necessary expertise required to adequately review submitted applications;

5.2.3 GREB will include at least five members represented by the following categories:

- At least two members who have expertise in relevant research disciplines, fields, and methodologies covered by GREB,
- At least one member who is primarily experienced in humanities or social science disciplines,
- At least one member who is knowledgeable in ethics,
- At least one member who is knowledgeable in the relevant laws,
- At least one community member who has no affiliation with Queen's University, and who is not part of the immediate family of a person who is affiliated with Queen's University,

- At least one member knowledgeable in considering privacy issues;
- At least one member who is either a researcher knowledgeable of First Nations, Métis, or Inuit (FNMI) issues, or an FNMI member of an identifiable Aboriginal community/Native Centre, or non-Aboriginal member closely associated with an FNMI community;

5.2.4 GREB's membership is loosely connected to the number of applications received each year, such that some departments will have more than one member whereas other departments are grouped to provide a representative member;

5.2.5 Queen's University senior administrators may not serve as GREB members;

5.2.6 Additional membership may be required by applicable legislation or guidelines.

5.3 Alternate Members

5.3.1 The GREB Chair or designee may ask alternate GREB member(s) to attend GREB meetings to draw on expertise in an area that may be relevant to a meeting's deliberations, or to establish a quorum for meeting(s) in the absence of regular GREB member(s);

5.3.2 Only alternate GREB members of comparable qualifications may substitute for a GREB member (e.g., a non-scientific member may not substitute for a scientific member);

5.3.3 The minutes shall document when an alternate GREB member replaces a primary GREB member;

5.3.4 All alternative members shall sign a Confidentiality Agreement and Conflict of Interest Disclosure Form.

5.4 GREB Chair/Vice Chair

- 5.4.1 Whenever possible and practicable, the GREB Chair and Vice Chair will be selected from experienced GREB members who have expressed interest in becoming the GREB Chair or Vice Chair and who are familiar with the applicable regulations and guidelines;
- 5.4.2 The Ethics Coordinator or designee updates the GREB membership roster to reflect changes in membership;
- 5.4.3 The GREB Ethics Compliance Advisor updates membership rosters when United States OHRP registration is required.

5.5 Ad Hoc Advisors

- 5.5.1 Ad hoc advisors have specific expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on GREB;
- 5.5.2 All ad hoc advisors shall sign a Confidentiality Agreement and Conflict of Interest Disclosure Form;
- 5.5.3 Ad hoc advisors may not contribute directly to GREB's decisions and their presence or absence shall not be used in establishing a quorum;
- 5.5.4 Documentation of key information provided by ad hoc advisors shall be summarized in the GREB minutes and, if available, the written report shall be placed in the GREB files.

5.6 Observers at GREB Meetings

- 5.6.1 The GREB may allow observers to attend its meetings;
- 5.6.2 Observers shall sign a Confidentiality Agreement and Conflict of Interest Disclosure Form;
- 5.6.3 Where GREB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed input if it is relevant and significant to the discussion;

5.6.4 Observers shall not participate when GREB discusses its decisions, reaches consensus, or votes on an application;

5.6.5 The minutes will reflect the presence of any observers as well as the expertise and contributions made, when applicable.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Composition of the GREB	v.201.001 2016FEB08	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).

Section 200:	GREB Organization
Title:	Management of GREB Membership
SOP Code:	202.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the management of the membership of GREB.

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.

The GREB Chair and the Director of Research Ethics Compliance are responsible for monitoring and managing GREB membership.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

GREB membership (e.g., appointment, terms) must be adequately managed to continue to meet applicable regulatory composition requirements and to maintain the appropriate diversity, experience, and expertise for the type and volume of research reviewed.

5.1 Appointments – Regular Members and Alternates

- 5.1.1 GREB members are appointed using the guidelines outlined in Terms of Appointment (below) and SOP 201.001, Composition of GREB;
- 5.1.2 A candidate may also self-nominate;
- 5.1.3 Community members (meeting membership requirements) are solicited from the greater local community;
- 5.1.4 Each GREB member selected is approved by the GREB Chair and the Director of Research Ethics Compliance using guidelines outlined in SOP 201.001, Composition of GREB;
- 5.1.5 Candidates selected to serve on GREB sign a Membership Appointment Letter, Confidentiality Agreement, and Conflict of Interest Disclosure Form;

- 5.1.6 The Chair shall encourage all GREB members to take the Course on Research Ethics (CORE) based on the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2, 2014).

5.2 Appointments – GREB Chair and Vice-Chair

- 5.2.1 The GREB Chair and Vice Chair are appointed using the guidelines outlined in Terms of Appointment (below) and SOP 201.001, Composition of GREB;
- 5.2.2 The GREB Chair and Vice-Chair sign a Confidentiality Agreement and Conflict of Interest Disclosure Form.

5.3 Ad Hoc Advisors

- 5.3.1 At the discretion of the GREB Chair or designee, individuals may be invited to GREB who have competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on GREB;
- 5.3.2 All ad hoc advisors sign a Confidentiality Agreement and Conflict of Interest Disclosure Form.

5.4 Terms of Appointment

- 5.4.1 The GREB Chair is appointed by the Vice-Principal (Research) in consultation with the Director of Research Ethics Compliance. The Chair should have at least two years of experience on GREB with knowledge of local policies, and national and international regulations;
- 5.4.2 The GREB Chair and Vice-Chair will serve for a three-year term to allow for continuity of the research ethics review process. However, the term of appointment can be extended when a Chair or Vice-

Chair possesses relevant and necessary expertise that would be difficult to replace;

- 5.4.3 Re-appointment of the GREB Chair for an additional term will be by the Vice-Principal (Research) under the advice of the Director of Research Ethics Compliance and agreement of the GREB Chair;
- 5.4.4 The GREB Chair shall seek a Vice-Chair from the membership to assist her, hir, or him when needed;
- 5.4.5 The Director of Research Ethics Compliance, with advice from the GREB Chair, will seek new GREB members through Department Heads, the GREB Chair, and other GREB members;
- 5.4.6 GREB's membership is loosely connected to the number of applications received each year, such that some departments have more than one member, whereas other departments are grouped to provide a representative member;
- 5.4.7 Each GREB member will serve for a three-year term to allow for continuity of the research ethics review process. However, the term of appointment can be extended when a member possesses relevant and necessary expertise that would be difficult to replace;
- 5.4.8 Re-appointment of a GREB member for an additional term requires mutual agreement of the GREB member and the GREB Chair or designee;
- 5.4.9 The GREB membership list will be posted on the website and updated each time the membership is changed;
- 5.4.10 GREB members' terms will be overlapping to preserve the experience level, expertise, and continuity of GREB. To maintain continuity, GREB will endeavour to have only one-third new members each year.

5.5 Qualifications and Training of GREB Members

- 5.5.1 Each GREB member will follow the qualification and training procedures outlined in SOP 206.001, Training and Education.

5.6 Resignations and Removals

- 5.6.1 A GREB member may resign before the conclusion of the three-year term upon provision of notice to the GREB Chair;
- 5.6.2 If a GREB member resigns before the end of the three-year term, the member's department will be asked to name another member to GREB;
- 5.6.3 GREB members may be asked to step down if they consistently miss more than 25 percent of the scheduled GREB meetings in their term;
- 5.6.4 The GREB Chair, in consultation with Director of Research Ethics Compliance, may remove GREB members at any time, if they are not fulfilling their designated GREB duties in a timely, competent, and ethical manner;
- 5.6.5 A GREB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest, or any other relevant behaviour that could be perceived as compromising his, her, or his ethical judgment;
- 5.6.6 Every effort will be made to recruit a similarly qualified replacement member prior to the departure of a member to preserve the level of GREB expertise and experience, maintain members from a wide constituency, and ensure the continuity of the functions of GREB.

5.7 Compensation

- 5.7.1 Compensation and reimbursement of expenses for GREB members will be according to Queen's University policies.

5.8 Liability and Coverage

- 5.8.1 All GREB members are insured for their research ethics review-related work by Queen's University's insurance policy (Canadian Universities Reciprocal Insurance Exchange), subject to the terms and conditions of that policy.

5.9 Documentation

- 5.9.1 The Ethics Coordinator will maintain an updated electronic GREB membership list and post it on the GREB website;
- 5.9.2 The GREB membership list is reviewed and updated as required, or with the initiation of new terms or conclusion/termination of existing terms;
- 5.9.3 The current GREB membership list and archived lists are maintained and available through University Research Services (URS);
- 5.9.4 Any documents signed by current and past GREB members (e.g., Membership Appointment Letters, Confidentiality Agreements and Conflict of Interest Disclosure Forms) will be maintained in the Office of University Research Ethics;
- 5.9.5 The Ethics Coordinator will maintain general and detailed GREB membership rosters. The general membership roster includes GREB member names and current affiliation (as applicable) and will be posted on the GREB website.
- 5.9.6 Additionally, a detailed list that contains GREB member contact information will be kept in the Office of Research Ethics. This list will be kept confidential, for access only by GREB members and GREB office personnel;
- 5.9.7 The GREB Ethics Compliance Advisor will update GREB registration with the US Office for Human Research Protection (OHRP), when applicable.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. GREB Membership Appointment Letter Template

8.0 REVISION HISTORY

SOP Title	Version	Updates
Management of GREB Membership	v.202.001 2016FEB08	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).

Section 200:	GREB Organization
Title:	Duties of GREB Members
SOP Code:	203.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the duties of the members of GREB.

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.

The GREB Chair is responsible for clearly articulating all required duties associated with membership to GREB to potential and current GREB members. GREB members and alternates are responsible for fulfilling their duties as specified in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Each GREB member's primary duty is to protect the rights and welfare of human research participants.

To fulfill their duties, GREB members must be well versed in regulations governing human participants' protection as well as humanities and social science research ethics, and policies germane to human research participant protection. GREB functions impartially and provides a fair hearing to all research proposals.

5.1 Attendance

- 5.1.1 Regular GREB members are expected to attend the regularly scheduled GREB meetings. GREB members may be asked to step down if they consistently miss more than 25 percent of scheduled GREB meetings;

- 5.1.2 GREB members must notify the GREB office if they will be absent for a GREB meeting to ensure that quorum can still be met and/or an appropriate alternate may attend instead;
- 5.1.3 Alternate GREB members are expected to attend the identified GREB meetings for which they have confirmed their availability to replace a regular GREB member, and/or a minimum of two GREB meetings per year;
- 5.1.4 GREB members are expected to be available for the entire GREB meeting. The Chair will ask department heads to ensure that no teaching activities are scheduled concurrently with GREB meeting times.

5.2 Terms of Duty

- 5.2.1 All members of GREB, including the GREB Chair and Vice-Chair, will be appointed for a term as specified in the GREB Terms of Appointment which is outlined in SOP 202.001, Management of GREB Membership.

5.3 Duties of GREB Members

- 5.3.1 All GREB members attending a GREB meeting are expected to review the relevant materials submitted for each item under review or consideration by GREB, to submit comments in advance of the GREB meeting, when applicable, and to be prepared to discuss and provide input for each agenda item at the full board meetings;
- 5.3.2 GREB members are expected to participate in the discussion of: full and delegated reviews, new policies, current activities, and adverse

events, as these are equally important discussions on the GREB meeting agenda;

- 5.3.3 Each GREB member is expected to fulfill specific duties based on the roles outlined below. More than one GREB member may fulfill each role;
- 5.3.4 All members are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise;
- 5.3.5 Community members are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective (e.g., readability of the application and materials given to participants);
- 5.3.6 Members knowledgeable in relevant law are expected to alert GREB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel to GREB;
- 5.3.7 Members knowledgeable in ethics are expected to guide GREB in identifying and addressing ethical issues related to the research under review;
- 5.3.8 Ad hoc advisors are individuals with competence in special areas where that expertise is helpful to GREB. Ad hoc advisors may be required to submit a written report and may participate via teleconference or attend the GREB meeting to lend their expertise to the discussions;
- 5.3.9 The GREB Chair or designee can ask an ad hoc advisor to attend a GREB meeting to draw on specific expertise in an area that may be relevant to GREB's review and deliberations of the research;
- 5.3.10 The GREB Chair or designee provides overall leadership to GREB.

5.4 Duties of GREB Chair and Vice-Chair

- 5.4.1 The GREB Chair is responsible for ensuring that the GREB review process is compliant with all applicable local policies, and national and international regulations and guidelines;
- 5.4.2 The GREB Chair can delegate any of the responsibilities, as appropriate, to a Vice-Chair or other qualified individuals. Any responsibilities that are delegated by the GREB Chair must be documented;
- 5.4.3 The GREB Chair or designee facilitates the review process based on GREB and Queen's University policies and procedures, SOPs, and applicable regulations and guidelines;
- 5.4.4 The GREB Chair or designee evaluates the level of risk of each research project and determines whether it should be a delegated or full review;
- 5.4.5 The GREB Chair or designee monitors GREB's decisions for consistency and ensures that decisions are recorded accurately and communicated to researchers in writing in a timely fashion;
- 5.4.6 The GREB Chair or designee ensures that all GREB members are free to participate in discussions during the GREB meetings;
- 5.4.7 The GREB Chair or designee performs or delegates authority to GREB members to perform delegated reviews;
- 5.4.8 The GREB Chair or Ethics Compliance Adviser reviews all course-based ethics applications;
- 5.4.9 The GREB Chair or designee signs off on all GREB decisions in writing;
- 5.4.10 The GREB Chair or designee reviews all amendments and renewals to make sure the ethical standards are met;

- 5.4.11 The GREB Chair or designee can suspend the conduct of any research project deemed to place participants at unacceptable risk pending discussion by the full board. The GREB Chair or designee can suspend the conduct of the research if he/she/ze determines that a researcher is not adhering to the GREB ethically cleared protocol or to GREB's policies and procedures;
- 5.4.12 The GREB Chair or designee in conjunction with the Director of Research Ethics Compliance will report on the activities of GREB to Queen's University through the Vice Principal (Research) on an annual basis, which is based on the fiscal year (May 1st – April 30th);
- 5.4.13 The GREB Chair or designee, in conjunction with the Ethics Compliance Advisor and Director of Research Ethics Compliance, and other Queen's University officials as applicable, ensures GREB members are informed of all new legislation, regulations, policies, and guidelines pertaining to human participant research, and shall advise GREB on policies and procedures related to research conduct;
- 5.4.14 The GREB Chair, in conjunction with the GREB Ethics Compliance Advisor and Director of Research Ethics Compliance, shall assess the educational and training needs of GREB members and office personnel, and will address any gaps identified;
- 5.4.15 The GREB Chair or designee reviews and approves GREB policies and procedures annually, to ensure GREB SOPs meet all current standards.
- 5.4.16 The GREB Vice-Chair or equivalent is responsible for performing the duties of the GREB Chair when the GREB Chair is unable to do so:

- The GREB Vice-Chair performs all responsibilities assigned by the GREB Chair,
- The GREB Vice-Chair assists with the overall operation of GREB.

5.5 Primary and Secondary Reviewers

- 5.5.1 For delegated reviews, GREB normally assigns two reviewers to each application when training is in-progress.
- 5.5.2 The second reviewer is asked to review the file and submit comments within one week to the lead reviewer (Chair). The lead reviewer (Chair) is expected to review the file and submit all changes within two weeks of receiving the application;
- 5.5.3 For delegated reviews, the reviewers will receive the researcher's responses and may either ask more questions or clear the file;
- 5.5.4 For full board reviews, the Chair will assign a primary (Chair) and a secondary reviewer to speak to the research projects at a GREB meeting. All GREB members are asked to submit their comments on the file before the GREB meeting;
- 5.5.5 For full board reviews, the primary (Chair) and secondary reviewers present their findings resulting from review of the GREB submission materials, provide an assessment of the soundness and safety of the research, and recommend specific action to GREB. They lead the discussion of the research project during the GREB meeting. The primary and secondary reviewers review additional material(s) as requested by GREB for the purpose of ethical clearance of the research.

5.6 Training and Education

5.6.1 GREB members are expected to follow training and education procedures outlined in SOP 206.001, Training and Education.

5.7 Conflict of Interest (COI)

5.7.1 GREB members are expected to follow conflict of interest procedures outlined in SOPs 105A.001, Conflict of Interest (COI).

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Duties of GREB members	v.203.001 2016FEB08	Original: This SOP was developed based on information from the TCPS2 (2014) and/or Queen's University previous documents or policies (using the format of CAREB/N2).

Section 200:	GREB Organization
Title:	GREB Office Personnel Serving as GREB Members
SOP Code:	204.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the duties of GREB office personnel serving as members of GREB.

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.

The GREB Chair or designee is responsible for clearly articulating all required duties associated with membership to GREB to potential and current GREB members.

GREB members and alternates are responsible for fulfilling their duties as specified in this SOP.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Each GREB member's primary duty is to protect the rights and welfare of human research participants.

To fulfill their duties, GREB members must be well versed in regulations governing human participants' protection as well as humanities and social science research ethics, and policies germane to human research participant protection. GREB functions impartially and provides a fair hearing to all research proposals. GREB office personnel serving as GREB members shall have knowledge, experience, and training comparable to what is expected of GREB members.

5.1 Duties

- 5.1.1 GREB office personnel who are designated as Board Members may attend convened meetings and participate in discussions, but they shall not be counted in determining a quorum nor shall they participate in any votes;

- 5.1.2 GREB office personnel who have been appointed to serve as GREB members may perform delegated reviews in accordance with the delegated review procedures outlined in SOP 402.001, Delegated Review;
- 5.1.3 The assignment of these tasks to GREB office personnel will be documented in GREB meeting minutes.

5.2 Appointment Criteria

- 5.2.1 GREB office personnel who serve as GREB members shall have knowledge, experience, and training comparable to what is expected of GREB members. GREB shall ensure that office personnel can fulfill their responsibilities as GREB members independently.

5.3 Training and Education

- 5.3.1 GREB office personnel serving as GREB members are expected to follow training and education procedures for GREB members outlined in SOP 206.001, Training and Education.

5.4 Conflict of Interest (COI)

- 5.4.1 GREB office personnel serving as GREB members are expected to follow conflict of interest procedures for GREB members outlined in SOPs 105A.001, Conflict of Interest (COI).

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Office Personnel Serving as GREB Members	v.204.001 2016FEB08	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).

Section 200:	General Administration
Title:	Management and Duties of Unit REBs
SOP Code:	205.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the creation, management and procedures of the membership of Unit Research Ethics Boards (UREBs).

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

The GREB Chair or designee is responsible for signing documents related to GREB review and ethical clearance of research. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the GREB Chair or the Director of Research Ethics Compliance.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

A system of delegated departmental review of research ethics applications has been established through Unit REBs (i.e., UREBs) for Social Sciences, Humanities, Sciences and Engineering research projects involving human participants for two reasons: a) to provide discipline-specific feedback to students conducting human research, and b) to assist with the high volume of applications from specific departments. It is the responsibility of the department heads to appoint members to Unit REBs, assign a UREB Chair, and provide administrative assistance as needed. Units with REBS review student ethics applications before these applications are sent to GREB. Units without REBS send all ethics applications directly to GREB.

5.1 Delegation of Signing Authority

- 5.1.1 The GREB Chair or designee may delegate signing authority for documents related to GREB review to UREB Chairs or UREB office personnel;

- 5.1.2 The GREB Chair or designee may only delegate signing authority to UREB Chairs and members or UREB office personnel who have the skill and knowledge necessary for the effective exercise of the authority;
- 5.1.3 The GREB Chair or designee may not delegate signing authority to ad hoc advisors or to independent contractors;
- 5.1.4 The GREB Chair or designee should clearly define the parameters of the delegated authority;
- 5.1.5 The GREB Chair or designee may delegate signing authority indefinitely or for defined periods of time (e.g., for absences);
- 5.1.6 Delegation of signing authority must be documented and kept on file and may need approval from the Director of Research Ethics Compliance.

5.2 Parameters of the Delegated Authority to UREBs

- 5.2.1 UREBs are delegated departmental research ethics boards that function on behalf and in cooperation with GREB;
- 5.2.2 The UREB Chair is responsible for notifying GREB of any change in membership.

5.3 UREB membership

- 5.3.1 The size of the UREB is based on the number of applications from each department. At a minimum, UREBs should consist of at least three members, one of whom is the UREB Chair;
- 5.3.2 The UREB Chair must be a faculty member of the department. Of the remaining members, there should be representation from both faculty members and graduate students in the department;
- 5.3.3 UREB members are expected to serve a minimum of one year. Each department is free to set its own term limits for UREB Chairs and members;

- 5.3.4 UREBs are encouraged to develop a structure to allow good communication among members to reach decisions on research ethics applications.

5.4 UREB Review

- 5.4.1 All student-based research projects involving human participants that do not meet the criteria for exemption must be reviewed by the researcher's departmental UREB; (For exemption criteria, see Chapter 2 of the TCPS2 (2014) or SOP 102.001, Research Activities Requiring GREB Review);
- 5.4.2 The UREB Chair or administrative assistant assigns each research ethics application to at least two of the UREB reviewers;
- 5.4.3 UREB's preliminary research ethics review informs researchers of any changes required in their research ethics application and reviews these changes before releasing the file to GREB with a recommendation for delegated or full board review;
- 5.4.4 If there are occasional situations where the UREB cannot fulfill its obligations to review a file, the GREB Chair will decide if the file should proceed to GREB delegated or full board review.

5.5 Appeals

- 5.5.1 In instances where the researcher does not agree with the UREB's research ethics application review or there are other concerns, the researcher or UREB may elect to forward the file to GREB where it will receive a full board review. In matters where privacy or confidentiality is a concern, the GREB Chair will make the decision about which correspondence between the UREB and the researcher will be attached to the application during the full board review.

6.0 REFERENCES

See References.

7.0 APPENDICES

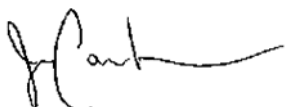
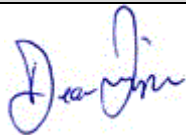
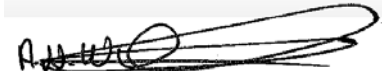
None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Unit REB Creation, Management and Procedures	v.205.001 2016FEB08	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).

Section 200	GREB Organization
Title:	Training and Education
SOP Code:	206.002
Effective Date:	2020DEC14

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 training and education requirements for GREB members, GREB office personnel and GREB researchers.

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

GREB members, GREB office personnel, and others charged with the responsibility for reviewing, granting ethical clearance, and overseeing human participant research should be well-versed in the regulations, guidelines, policies, and ethical principles applicable to human participant research. The GREB Chair, in collaboration with GREB office personnel, may advise Queen's University on policies and procedures related to the ethical conduct of research involving human participants. Adequate training and education in these areas is critical for GREB to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner.

5.1 Training and Education – GREB Members

- 5.1.1 The GREB Chair or designee and GREB office personnel will provide new GREB members with a general overview of the policies and procedures pertinent to GREB meeting functions and GREB member expectations, as well as an orientation to the principles and guidelines for research ethics;
- 5.1.2 The GREB Chair or designee, in conjunction with GREB office personnel, will assess educational and training needs of GREB members to identify and address any gaps in knowledge, skills, or competencies required to fulfil their duties;
- 5.1.3 GREB performance feedback will be provided on an ongoing basis by the GREB Chair to GREB office personnel as appropriate;
- 5.1.4 New GREB members will receive an orientation before beginning their formal duties;
- 5.1.5 All new GREB members will be required to complete the online tutorial on the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) Course on Research Ethics (CORE);
- 5.1.6 GREB members are expected to participate in the orientation process, which may include, but is not limited to:
 - Background on GREB (e.g., Terms of Reference, governance structure, process flowchart),
 - Policies and Procedures (e.g., relevant SOPs and associated forms, Letter of Information, Consent Form checklist),
 - System training,
 - Member information (e.g., meeting schedule, membership list, information and guidelines for members, reviewers' guide),
 - Regulatory and guidance documents,
 - Other member-specific information (e.g., copy of signed Confidentiality Agreement and Conflict of Interest Disclosure Form, Membership Appointment Letter),

- Resource information (e.g., list of training and education references, relevant articles);
- 5.1.7 As part of their orientation, new GREB members will be offered the opportunity to observe at least one GREB meeting prior to commencing their GREB member duties;
- 5.1.8 GREB members are encouraged to attend conferences and other educational sessions pertaining to human participant research protection, such as the Canadian Association of Research Ethics Board (CAREB) annual general meeting and CAREB regional meetings. The GREB office will support such activities to the extent possible and as appropriate to the responsibilities of GREB members and GREB office personnel. Conference attendance is based on availability of funding and other practical considerations (e.g., timing, conference location);
- 5.1.9 Ongoing ethics education in areas germane to GREB members' responsibilities may be provided at GREB meetings;
- 5.1.10 All GREB members and any relevant office personnel will be invited to attend the annual Spring Retreat, at which current ethical issues are discussed in depth. The recommendations elicited from these retreats are used to guide the development of GREB policies and procedures;
- 5.1.11 Applicable new or revised guidelines and SOPs will be disseminated to new GREB members;
- 5.1.12 GREB members are encouraged to engage in self-directed learning in research ethics and in the conduct of research to enhance their ability to fulfill their responsibilities.

5.2 Training and Education – GREB Office Personnel

- 5.2.1 The Manager, Research Ethics Compliance or designee, will provide new GREB office personnel with an overall orientation to GREB including a general overview of the policies and procedures pertinent to their role in support of GREB;
- 5.2.2 The Manager, Research Ethics Compliance or designee will assess educational and training needs of GREB office personnel to identify and address any gaps in knowledge, skills, or competencies required to fulfill their duties;
- 5.2.3 New GREB office personnel will receive an orientation package. Before commencing their official duties in the GREB office, GREB office personnel are expected to read and become familiar with the information;
- 5.2.4 New GREB office personnel will receive training on GREB SOPs and will be expected to be knowledgeable and compliant with the SOPs;
- 5.2.5 New GREB office personnel are required to complete the online tutorial on the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) Course

on Research Ethics (CORE) and are encouraged to complete additional and ongoing relevant education and training in research ethics and the conduct of research;

- 5.2.6 GREB office personnel are encouraged to attend conferences and educational sessions pertaining to human participant research protection, such as the CAREB annual general meeting and CAREB regional meetings. The GREB office will support such activities to the extent possible and as appropriate to the responsibilities of GREB members and GREB office personnel. Conference attendance is based on availability of funding and other practical considerations (e.g., workload, staffing, conference location);
- 5.2.7 New or revised guidelines and SOPs will be disseminated to GREB office personnel;
GREB office personnel are encouraged to engage in self-directed learning to enhance their ability to fulfill their responsibilities.

5.3 Training and Education – Researchers

- 5.3.1 All project team members performing significant study-related duties, including those who have access to study data, are required to complete the online tutorial on the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Course on Research Ethics (CORE). This policy applies to all faculty, librarians, archivists, post-doctoral fellows, medical residents, graduate and undergraduate students, staff and external applicants;
- 5.3.2 Researchers are also encouraged to complete additional and ongoing relevant education and training in research ethics and the conduct of research;
- 5.3.3 Proof of equivalent ethics training must be attached to the ethics application in TRAQ for all project team members performing significant-study related duties. In some circumstances an exemption may be granted for the completion of ethics training. In these cases the exemption from the Office of Research Ethics Compliance must be attached to the ethics application in TRAQ;
- 5.3.4 The Office of Research Ethics Compliance may take other ethics training certifications in lieu of the CORE tutorial (e.g., Good Clinical Practice, Biomedical Ethics tutorial – CITI); however, this is at the discretion of the Office of Research Ethics Compliance. Proof of equivalent ethics training must be attached to the ethics application in TRAQ.

5.4 Documentation of Training and Education

- 5.4.1 GREB members and GREB office personnel are asked to document their training sessions (e.g., relevant workshops, seminars, and conferences) in their curriculum vitae;

- 5.4.2 GREB agendas and minutes will record the distribution of any educational materials presented at the GREB meetings.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Training and Education	v.206.001 2016FEB08	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).
Training and Education	v.206.002 2020DEC14	<ol style="list-style-type: none">1. Section 5.1 Training and Education – Researchers added.2. Documentation of Training and Education was re-numbered to section 5.4 instead of section 5.3.3. Updates made to SOP to reflect the new position of Manager, Research Ethics Compliance.4. Updates made to for new policy to require CORE training for all applicants as of Dec 2, 2019.5. Terminology updates

Section 300:	Functions and Operations
Title:	GREB Submission Requirements and Administrative Review
SOP Code:	301.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the GREB submission requirements and administrative review procedures. This SOP applies to all submissions including, but not limited to: applications for initial review, amendments or changes to ethically cleared research, and any new information.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

GREB members must rely on the documentation provided by the researcher for initial reviews and renewals of ethical clearance. Therefore, the materials submitted must provide sufficient information to conduct the review and to make the required determinations.

GREB is supported by administrative procedures that ensure that GREB members not only have adequate time to assess the proposed research, but also that the materials they receive allow them to adequately assess whether or not the research submission meets the criteria for GREB ethics clearance.

The requirements for GREB submissions are made available to all researchers. GREB office personnel are responsible for maintaining and disseminating this information to researchers.

5.1 Submission Requirements

- 5.1.1 The required documents, format, submission dates, and procedures are outlined on the GREB website and within the online submission program TRAQ (Tools for Research at Queen's).

- 5.1.2 Researchers can access the Ethics Application Form via the GREB website at <http://www.queensu.ca/urs/ethics/general-research-ethics-board-greb>. For first-time users, education is available under the heading of TRAQ; a registration process may be necessary;
- 5.1.3 All research applications must be submitted electronically including:
- Ethics Application Forms,
 - Instructor's Course-Based Application Forms,
 - Amendment Forms,
 - Renewal Forms,
 - Adverse Event Forms;
- 5.1.4 Additional resources, such as templates and checklists, can be found on the GREB website, which may include, but are not limited to:
- GREB Application guidelines,
 - Submission checklist,
 - Informed Consent Form required elements checklist,
 - Examples of Letters of Information and Consent Forms;
- 5.1.5 All Queen's University research students at the graduate and undergraduate level are required to complete the latest edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2 - 2014) Course on Research Ethics (CORE) and submit a copy of the completion certificate with their ethics application. CORE is additionally recommended for all faculty researchers;
- 5.1.6 All Queen's University research students at the graduate and undergraduate level must have their supervisor review the application and have the supervisor submit an email/letter of approval that the project can go forward to UREB and/or GREB review;

- 5.1.7 GREB may request any additional documentation it deems necessary for the ethics review or research ethics oversight;
- 5.1.8 **Research Requirements:** The research question and methodology should be written in sufficient detail to permit evaluation of the ethical aspects of the project. As a general rule, reviewers need to see a copy or a description of all items that participants in the project will encounter (e.g., documents, procedures, instructions, stimuli). Such items include, for example, simple demographic questionnaires, physical measurements (e.g. height), and perceptual stimuli (e.g., a small flashing red light). The research should include all of the required elements applicable to the research such as, but not limited to:
- Research rationale and objectives,
 - Design and detailed description of methodology,
 - How information will be collected (e.g., observation, interview, questionnaire, measurements),
 - The population to be studied,
 - Eligibility/exclusion criteria,
 - Sample size,
 - Reimbursement, compensation, or gifts,
 - Recruitment and consent process, including the Letter of Information, Consent Form, and communication scripts,
 - Research interventions, and justification for deception if used,
 - Assessment of risks and strategies to minimize these risks,
 - Benefits,
 - Measures in place to protect privacy and confidentiality,
 - Data security and storage;

- 5.1.3 More information regarding application requirements is available in SOP 402.001, GREB Delegated Review, and SOP 403.001, GREB Full Board Review.

5.2 Administrative Review Procedures

- 5.2.1 The TRAQ file number is generated by the TRAQ electronic system at the time the application is initiated;
- 5.2.2 A unique second file number is assigned to each submission at the time of the receipt of the application by the Ethics Coordinator or designee;
- 5.2.3 The Ethics Coordinator or designee performs an administrative review of the submission for overall completeness (especially CORE certificate and supervisor's statement of preparedness) ;
- 5.2.4 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the GREB reviewers will follow up with the researcher and/or research coordinator to request the required information for inclusion with the submission;
- 5.2.5 For submissions requiring full board review, the Ethics Coordinator or designee includes the application into the agenda of the next GREB meeting. Primary and secondary reviewers are designated by the GREB Chair and informed by the Ethics Coordinator before the agenda is completed;
- 5.2.6 For submissions to be reviewed by the delegated review procedures, the Ethics Coordinator or designee, in consultation with the GREB Chair, will assign the application to GREB members or the GREB Chair will complete the review with GREB members.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Submission Requirements and Administrative Review	v.301.001 2016FEB08	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).

Section 300:	Functions and Operations
Title:	GREB Meeting Administration
SOP Code:	302.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the required activities for the preparation, management, and documentation of Full Board meetings of GREB.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The GREB meeting agenda provides the meeting content and establishes a sequence of review. It also provides an overview of all items that have been previously (i.e., during the preceding time between GREB meetings) reviewed and ethically cleared by delegated review procedures. Information documented in the GREB meeting agenda provides the foundation for the GREB meeting minutes.

The GREB meeting minutes document the actions that occur during a GREB meeting. The minutes should enable a reader who was not present at the GREB meeting to determine how and with what justification the GREB arrived at its decisions. They should also provide GREB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

Although the delegated review procedure is used most frequently for GREB reviews because of the low risk involved in most applications, when the GREB full board review procedure is deemed necessary by the GREB Chair or designee, a quorum must be present at the GREB meeting. A quorum is defined as having as a majority of members present (50% + 1).

5.1 Agenda Preparation

5.1.1 The GREB agenda follows a structured format that is consistent for all meetings. It includes the following items:

- Acceptance of the Agenda,
- Conflict of Interest declarations and confidentiality reminders,
- Minutes of the last meeting,
- Business arising from the last meeting,
- Full Board Reviews,
- Report on all delegated reviews since the last meeting,
- Protocols for assisted delegated review,
- Amendment Report,
- Renewal Report,
- Adverse Events Report,
- Actionable Items,
- Report from the Chair,
- Other and Continuing Business,
- New Business,
- Adjournment;

5.1.2 Prior to the meeting, the Ethics Coordinator develops a summary of all delegated reviews that have been cleared since the last GREB meeting. The Ethics Coordinator also attaches all of the comments made by the reviewers and asks members to reduce this list to the most relevant points prior to the GREB meeting. These summary reports and summary comments are included in the agenda;

5.1.3 The Ethics Coordinator or designee, in consultation with the GREB Chair or designee as necessary, reviews the agenda, confirms GREB meeting attendance, and assigns the reviewers for any full board reviews;

- 5.1.4 The reviewer assignment and the agenda are issued in a timely manner prior to the GREB meeting date. GREB members attending the GREB meeting will receive a copy of the GREB meeting agenda;
- 5.1.5 The minutes of the previous meeting include a summary of the discussion and the final letter(s) from full board reviews that were sent out to researchers;
- 5.1.6 At each GREB meeting, there is a complete list of all of the amendments and all of the renewed projects. These are presented to GREB members in organized charts for approval at the GREB meetings;
- 5.1.7 The Ethics Coordinator or designee adds any other items for information or discussion at the GREB meeting (e.g., Report from the Chair, SOPs, educational articles, presentations, reports);
- 5.1.8 The GREB Chair or designee invites the appropriate alternate GREB member to the meeting when a regular GREB member is not able to attend. Ad hoc advisors will receive copies of relevant submissions;
- 5.1.9 Any changes to the agenda, including convening unscheduled meetings to deal with contingencies, are communicated to all GREB members and GREB office personnel. The Ethics Coordinator or designee also may issue an updated agenda notice depending on the nature of the changes;
- 5.1.10 The agenda is drafted by the Ethics Coordinator or designee and ratified by the GREB Chair.

5.2 Primary and Secondary Reviewers

- 5.2.1 Prior to the meeting, the Ethics Coordinator or designee, in consultation with the GREB Chair or designee, will assign a primary and secondary reviewer for each full board review application. The assigned reviewers will receive early notification of this assignment;
- 5.2.2 GREB members will not be assigned as reviewers on submissions for which they are a researcher or co-researcher or in which there is a declared Conflict of Interest (COI);
- 5.2.3 If any of the assigned reviewers declare a COI, the submission is reassigned to another reviewer.

5.3 In Advance of the GREB Meeting

- 5.3.1 All GREB members are expected to conduct a review of each agenda item prior to the GREB meeting, including previous GREB meeting minutes on the agenda and any attachments to the agenda for review or discussion;
- 5.3.2 The primary and secondary reviewers will conduct in-depth reviews of their assigned submissions and should submit reviewer comments prior to the GREB meeting. The primary reviewer should be prepared to lead the discussion at the GREB meeting;
- 5.3.3 GREB members who are not assigned as primary or secondary reviewers on full board reviews are expected to submit their individual comments for each submission in TRAQ prior to the meeting;
- 5.3.4 All GREB members should be prepared to present their comments and participate in the discussion at the GREB meeting.

5.4 During the GREB Meeting

- 5.4.1 A quorum must be present to proceed with a GREB meeting;
- 5.4.2 Should quorum fail during a Full Board meeting (e.g., through recusal of GREB members with Conflicts of Interest or early departures), GREB may not make further decisions unless quorum can be restored;
- 5.4.3 An alternate GREB member may attend in the place of a regular GREB member to meet quorum requirements. When a GREB member and the alternate both attend the GREB meeting, only one is allowed to participate in the deliberations and final decisions regarding ethical clearance;
- 5.4.4 Although discouraged, a GREB member who cannot be physically present during a GREB meeting may participate via videoconference or teleconference. GREB members participating by videoconference or teleconference count toward quorum;
- 5.4.5 Ad hoc advisors will not be used to establish a quorum;
- 5.4.6 GREB members recusing themselves due to a COI are not counted toward quorum;
- 5.4.7 Only those GREB members present (i.e., in person, or via videoconference or teleconference) at the GREB meeting may participate in the deliberation and final decision regarding ethical clearance; however, written comments from absent members can be submitted for review for consideration of an application;
- 5.4.8 When there is less than full attendance at a GREB meeting, decisions should be adopted only when the members in attendance have the specific expertise, relevant competence, and knowledge necessary to provide an adequate review;
- 5.4.9 GREB may be required to convene unscheduled meetings due to exigencies (i.e. publically declared emergencies);
- 5.4.10 During publicly declared emergencies, the GREB Chair or designee may use discretion to conduct a GREB meeting with all GREB

members attending via simultaneous videoconference or teleconference, provided all members have access to the review materials and quorum is met (see TCPS2 (2014), Chapter 6);

- 5.4.11 GREB attempts to forego the monthly meetings in July and August, if possible. For these months only, full board reviews are handled by a minimum of five GREB members present to make the decisions. All GREB members are encouraged to submit their comments, even if not present for the discussion;
- 5.4.12 Observers may be invited or permitted to attend GREB meetings, subject to the agreement of GREB and execution of a Confidentiality Agreement. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the GREB meeting;
- 5.4.13 If requested, researchers may (in person or via teleconference) attend the GREB meeting to present their research and respond directly to any comments or questions raised by GREB, subject to the agreement of GREB; however they cannot participate in deliberations or votes;
- 5.4.14 Any individual not listed on the official GREB membership roster may not participate in the decisions of GREB;
- 5.4.15 At the meeting, lead reviewers on delegated review reports are asked to comment on their reports. These delegated review reports serve to educate and train GREB reviewers in applying the same standards across applications. Once all delegated review reports have been presented and discussed, GREB is asked to approve the delegated review reports. If any questions arise about any reports, they are clarified before the next meeting with more information and approved at the later meeting.

5.5 Meeting Minutes Preparation

- 5.5.1 The Ethics Coordinator or designee will draft the GREB meeting minutes including attendance, key discussions, decisions, and votes;
- 5.5.2 The key GREB discussions and decisions for submissions are recorded;
- 5.5.3 GREB's concerns, clarifications, and recommendations to researchers as discussed at the GREB meeting are drafted by the Ethics Coordinator, and then edited by the Chair and primary and secondary reviewers before being sent to the researcher via TRAQ;
- 5.5.4 If the concerns are consequential, then the letter is sent to the entire GREB before being sent to the researcher via TRAQ;
- 5.5.5 The information documented in TRAQ is included in the GREB meeting minutes;
- 5.5.6 The meeting may be audio tape recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft of the minutes;
- 5.5.7 The minutes are intended to reflect what GREB decided, how it resolved controverted issues, and any determinations required by the regulations;
- 5.5.8 The draft minutes must be completed prior to the next GREB meeting and vetted by the Chair.

5.6 Meeting Minutes Approval

- 5.6.1 The minutes are made available at the next appropriate GREB meeting and are presented at the GREB meeting for review and approval;
- 5.6.2 GREB motions and votes on the previous GREB meeting minutes are recorded in the current GREB meeting minutes;

5.6.3 If the previous GREB meeting minutes are approved pending revisions, the Ethics Coordinator or designee makes the required changes, and, unless the GREB requests further review of the minutes prior to approval, the Ethics Coordinator or designee records the minutes as approved.

5.7 Documentation

5.7.1 The GREB meeting minutes include the following items:

- Date, place, and time the GREB meeting commenced and adjourned,
- Names of GREB members in attendance (present, teleconference, videoconference),
- Names of GREB members absent,
- Names of GREB office personnel present at the meeting,
- Presence of observers,
- Use of ad hoc advisors and their specialty,
- List of declared Conflicts of Interest, a summary of any discussions, and the decision taken by GREB to address concerns raised in the discussions (as applicable),
- Decisions taken by GREB regarding ethical clearance for each submission, as applicable,
- A summary of key discussions and disputed issues and their resolution for each submission, as applicable,
- The basis for requiring changes or for not granting ethics clearance for submissions,
- GREB member(s) recused related to Conflicts of Interest for each submission requiring a decision,
- Number(s) voting for, against, or abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda;

5.7.2 All GREB meeting agendas and minutes are retained in the GREB records;

5.7.3 The agendas, GREB meeting minutes, and review documents are confidential and will not be released or made available unless required for inspection or auditing purposes.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Meeting Administration	v.302.001 2016FEB08	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).

Section 300:	Functions and Operations
Title:	Document Management
SOP Code:	303.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the requirements for electronic documentation and signatures, and document management, including document retention and document archiving. This SOP applies to documents submitted to GREB for review, as well as to all GREB administrative documents.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The GREB office must retain all relevant records (e.g., documents reviewed and cleared or not cleared, GREB meeting minutes, correspondence with researchers, written SOPs, GREB membership rosters) to provide a complete history of all actions related to the GREB review and clearance of submitted research. Such records must be retained for the length of time required by applicable regulations and guidelines.

Relevant records must be made accessible to authorized regulatory authorities, representatives of these organizations, researchers, and funding agencies within a reasonable time upon request.

5.1 Research-Related Documents

5.1.1 University Research Services (URS) retains the submission materials for all research that have been submitted for GREB review and have been either cleared, acknowledged, or not ethically cleared;

5.1.2 Research-related documents include, but are not limited to, the following (as applicable):

- Initial application form,

- Correspondence between GREB and the researcher, including, but not limited to, GREB clearance letters and requests for modifications;
- Records of ongoing review activities such as:
 - Reportable event submissions, including adverse events, privacy breaches, any investigations into allegations of serious or continuing non-compliance, and reports of inspections and audits by regulatory agencies or others,
 - Modifications to the application including amendments to the research and/or any changes to the consent processes and participant materials,
 - Renewal applications,
- Copies of correspondence between GREB and regulatory agencies,
- Reports of any complaints received by GREB and their resolution.

5.2 GREB Administrative Documents

5.2.1 University Research Services (URS) retains all administrative records related to GREB review activities;

5.2.2 GREB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all GREB meetings,
- Submitted GREB member reviews,
- GREB member records:
 - Current and obsolete GREB membership rosters, including alternate GREB members,
 - GREB membership Appointment Letters,

- Signed Conflict of Interest Disclosure Forms and Confidentiality Agreements,
- Current and obsolete SOPs,
- Current and obsolete documentation of the GREB Chair or designee's delegation of authority, responsibilities, or specific functions,
- Records of registration of GREB with the US Office of Human Research Protection, if applicable, and GREB membership updates,
- Submission deadlines, guidelines for submitting applications, and all associated attachments/templates.

5.3 Document Access, Storage, and Archiving

- 5.3.1 All electronic documents associated with GREB ethics applications are housed in TRAQ, which is an online system that is accessible only to authorized individuals. Each user is provided with a unique user ID and password to login to the system;
- 5.3.2 Access to individual research projects and related documents, and researcher profiles is role-based to ensure that users only have access to documents and activities that are required by their role;
- 5.3.3 System validation checks are conducted by Process Pathways to ensure accuracy, reliability, and program consistency;
- 5.3.4 Secure, time stamped audit trails are in place to record the data and time of activities, which are identifiable by user;
- 5.3.5 The GREB TRAQ and administrative electronic records are stored on Queen's University's local server with back-up, disaster, and recovery systems in place. Access to electronic GREB TRAQ and administrative files are accessible only to authorized individuals;

- 5.3.6 GREB closed paper research files are securely stored in the Office of Research Ethics or archived with Iron Mountain, an off-site storage facility.

5.4 Electronic Signatures

- 5.4.1 All electronic signatures on documents include the printed name of the signer, the date/time the signature was executed, and the meaning associated with the signature (e.g., review, clearance, responsibility, authorship);
- 5.4.2 All documents containing electronic signatures will be encrypted, to ensure the signatures cannot be excised, copied, transferred, or manipulated;
- 5.4.3 Each electronic signature will be verified as an individual's electronic signature by GREB office personnel. Each electronic signature will be unique (i.e., not reused by or reassigned to another individual);
- 5.4.4 All electronic signatures used on GREB documentation are intended to be the legally binding equivalent of traditional handwritten signatures.

5.5 Confidentiality and Document Destruction

- 5.5.1 All submissions received by GREB are considered confidential and are accessible only to GREB members (including the GREB Chair and Vice-Chair), as well as to applicable Queen's University officials and GREB office personnel;
- 5.5.2 Relevant research projects' files and associated documents may be made accessible to other Queen's University officials, as well as to funding agencies and/or industry sponsors (if applicable), if researchers or their research teams submit a request for guest access to the research;

- 5.5.3 The GREB Chair, in consultation with the Director of Research Ethics, may make relevant research projects and associated documents accessible to “authorized representatives of the institution, researchers, sponsors and funders when necessary to assist internal and external audits, or research monitoring, and to facilitate reconsideration or appeals” (see TCPS2, 2014, Article 6.17);
- 5.5.4 GREB will retain required records (e.g., research-related or GREB administrative documents, as applicable) for a minimum of 10 years after completion/termination of the trial, or for the maximum amount of time stipulated in any applicable governing regulations;
- 5.5.5 Any confidential materials in paper format in excess of the required documentation will be shredded;
- 5.5.6 Researchers may access the Queen’s Research Data Management Services or the Queen's Research Data Centre for long-term storage of their research data.

5.6 Storage of Confidential Personal Identifying Information

- 5.6.1 Any information that is obtained by GREB that is confidential in nature and that can personally identify an individual (e.g., name and contact information of a complainant) will be kept securely on hard copy in University Research Services (URS). Any electronic copies of personally identifying information will be de-identified and stored electronically in a secure network drive with restricted access. In addition, a copy of the de-identified information will be attached to the TRAQ file within the secure electronic system.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Document Management	v.303.001 2016FEB08	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).

Section 400:	Review of Research
Title:	Unit REB Reviews
SOP Code:	401.001
Effective Date:	2016MARCH07

Site Approvals

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

1.0 PURPOSE

This standard operating procedure (SOP) describes the Unit REB processes in some departments for initial review of student-based research applications and UREB's recommendation for the level of review by GREB.

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 Unit REB members, Unit REB administrative staff, and GREB office personnel are responsible for ensuring that the requirements of this SOP are met.

GREB is responsible for the establishment of Unit REBs and the responsibilities they are assigned. The GREB Chair or designee is responsible for overseeing these assigned duties and recommending changes as needed. The Ethics Compliance Adviser is responsible for monitoring the functioning of Unit REBs to ensure compliance with TCPS2 (2014) guidelines and Queen's policies. The Ethics Coordinator is responsible for ensuring that the Unit REB members are entered as reviewers into the Unit REB on-line Human Ethics Application System.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

A system of delegated departmental review of research ethics applications has been established through Unit REBs (i.e., UREBs) for Social Sciences, Humanities, Sciences and Engineering research projects involving human participants for two reasons: a) to provide discipline-specific feedback to students conducting human research, and b) to assist with the high volume of applications from specific departments. It is the responsibility of the department heads to appoint members to Unit REBs, assign a UREB Chair, and provide administrative assistance as needed. Units with REBs review student ethics applications before these applications are sent to GREB. Units without REBs send all ethics applications directly to GREB.

5.1 Parameters of the Delegated Authority to UREBs

- 5.1.1 UREBs are delegated departmental research ethics boards that function on behalf and in cooperation with GREB;
- 5.1.2 The UREB Chair is responsible for notifying GREB of any change in membership.

5.2 UREB membership

- 5.2.1 The size of the UREB is based on the number of applications from each department. At a minimum, UREBs should consist of at least three members, one of whom is the UREB Chair;
- 5.2.2 The UREB Chair must be a faculty member of the department. Of the remaining members, there should be representation from both faculty members and graduate students in the department;
- 5.2.3 UREB members are expected to serve a minimum of one year. Each department is free to set its own term limits for UREB Chairs and members;
- 5.2.4 UREBs are encouraged to develop a structure to allow good communication between members to reach decisions on research ethics applications.

5.3 UREB Review

- 5.3.1 All student-based research projects involving human participants that do not meet the criteria for exemption must be reviewed by the researcher's departmental UREB (for exemption criteria, see Chapter 2 of the TCPS2 (2014) or SOP 102.001, Research Activities Requiring GREB Review);
- 5.3.2 The UREB Chair or administrative assistant assigns each research ethics application to at least two UREB reviewers;

- 5.3.3 UREB's preliminary research ethics review informs researchers of any changes required in their research ethics application and reviews these changes before releasing the file to GREB with a recommendation for delegated or full board review;
- 5.3.4 If there are occasional situations where the UREB cannot fulfill its obligation to review a file, the GREB Chair will decide if the file should proceed to GREB as a delegated or full board review.

5.4 Appeals

- 5.4.1 In instances where the researcher does not agree with the UREB's research ethics application review or there are other concerns, the researcher or UREB may elect to forward the file to GREB where it will receive a full board review. In matters where privacy or confidentiality is a concern, the GREB Chair will make the decision about which correspondence between the UREB and the researcher will be attached to the application during the full board review.

6.0 REFERENCES

TCPS2 (2014) Articles 2.5, 6.12.

7.0 APPENDICES

1. [Student Course-Based Research Assignment Guidelines](#)

8.0 REVISION HISTORY

SOP Title	Version	Updates
Unit REB Reviews	v.401.001 2016MAR07	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 400:	Review of Research
Title:	GREB Delegated Reviews
SOP Code:	402.001
Effective Date:	2016MARCH07

Site Approvals

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

1.0 PURPOSE

This SOP describes the decisions that the GREB may make during the Delegated review of proposed research for ethical acceptability.

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.

The GREB Chair or designee is responsible for ensuring that: (1) each ethics application qualifies for delegated review based on criteria set out by the TCPS2 (2014) and this SOP; (2) GREB members act with due diligence in completing the review; (3) changes needed are communicated clearly to the researchers; (4) decisions are made in a timely manner; and (5) researchers are informed of their responsibilities for the duration of the application.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

As described in Article 6.12 of the TCPS2 (2014) guidelines, GREB uses a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full board review by GREB should be the default requirement for all research involving human participants unless GREB decides to authorize delegated review based primarily on the risks or harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow GREB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research. This principle also applies to course-based research assignments.

In practice, proportionate review implies different levels of GREB review for different research projects. The two levels used by GREB are full board review or delegated review by one or more experienced GREB members, as determined by the GREB Chair

or designee. In the case of instructor course-based research assignments ethics applications, the GREB Chair or designee will conduct the reviews.

The GREB's primary duty is to protect the rights and welfare of human research participants. However, GREB's secondary role is to support the research enterprise by assisting researchers in fulfilling their obligations to research participants according to the TCPS2 (2014) guidelines and Queen's policies. In this capacity, GREB members endeavour to provide feedback in a positive and supportive manner, regardless of whether it is a delegated review or a full board review.

5.1 Determination of Qualification for Delegated Review:

5.1.1 Full board review is the default for new research projects submitted to the GREB (Article 6.12, TCPS2 [2014]);

5.1.2 Article 6.12 states: "In keeping with a proportionate approach to research ethics review, the selection of the level of (G)REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review)";

5.1.3 The Application Section 6.12 describes research that may be eligible for delegated review:

- Research project that is confidently expected to involve minimal risk,
- Minor or minimal risk amendments/changes to ethically cleared research,
- Annual renewals of approved minimal risk research,
- Annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal,
- Annual renewals of more than minimal risk research where the remaining research-attributable risk is minimal;
- Annual renewals of more than minimal risk research in which there has been: i) no significant changes to the research, ii)

no increase in risk to (or other ethical implications for) the participants since the most recent review by the GREB, and
iii) the GREB Chair has determined that the delegated review process is appropriate.

5.2 Delegated Review Procedures:

- 5.2.1 The GREB Chair or designee will examine all ethics applications to determine if there are more than minimal risks and decide whether or not the file should be assigned a full board review or a delegated review;
- 5.2.2 The GREB Chair may also base the decision regarding delegated to full board review on the recommendation of the UREB as well as an examination of the application and attachments to determine if there are other concerns related to the research methods, recruitment practices, participant population, rights, safety and well-being of research participants, confidentiality of data, and all regulatory and ethics guidance requirements as applicable;
- 5.2.3 Since most GREB ethics applications are of minimal or minor risk to participants, they are assigned to delegated review;
- 5.2.4 The Ethics Coordinator, with advice from the GREB Chair or designee, will assign one or two GREB members to each delegated review based on members' experience, expertise, and level of training;
- 5.2.5 The GREB Chair or GREB reviewers must not be in a conflict of interest situation with either the researchers or the research; if such a conflict occurs, the reviewer must report the conflict and a new GREB member will be assigned to the delegated review;
- 5.2.6 If GREB reviewers have concerns with their level of experience and expertise to review the application or if they believe it should be

reviewed by the full board, they can refer the application to the GREB Chair;

- 5.2.7 If an application is referred by reviewers, the GREB Chair will review the application or assign other GREB member(s) to the review team or, if appropriate, assign the application to a GREB full board review;
- 5.2.8 The GREB reviewers will either propose that the ethics application be cleared or ask for clarifications and/or modifications by the researchers;
- 5.2.9 Researchers will modify the ethics application and attachments to address the GREB reviewers' comments or may rebut the request for certain changes;
- 5.2.10 The responsibilities for additional review and the decision regarding ethics clearance conditions lies with the GREB reviewers. If, however, they have concerns with the application or their level of experience and expertise, they should refer the application to the GREB Chair;
- 5.2.11 Normally the reviews and corrections are completed within one or two exchanges with the researchers at which time the reviewers will either propose that the ethics application be cleared, or refer the application to the Chair for a full board review;
- 5.2.12 If the research cannot be granted ethics clearance after revisions are requested in the delegated review process, the research must be reviewed by the full board at GREB meeting.

5.3 Delegated Review of Course-Based Research Projects

- 5.3.1 The Applications Section of Article 6.12 states: "The REB should establish written procedures and set out criteria for determining which categories of research proposal may be eligible for different types of review, and specify who is responsible for implementing

and overseeing the approval mechanisms.” Based on this Article, GREB has established a system for student course-based research assignments;

- 5.3.2 Instructors are required to submit an Instructor Course-Based Research Assignment Ethics Application Form in TRAQ. This application form is streamlined for course assignments with instructors expected to submit their assignment outline and all materials that will be given to the students;
- 5.3.3 Some course-based ethics applications have been grandfathered into the TRAQ system if the application has already been submitted;
- 5.3.4 The Ethics Compliance Advisor or GREB Chair will normally review all instructors’ course-based applications submitted in TRAQ. The procedures for the review follow 5.2 outlined above;
- 5.3.5 Undergraduate and graduate independent study courses and thesis courses do NOT qualify as course-based research. These applications will be reviewed through the regular delegated or full board review process;
- 5.3.6 The criteria for course-based research projects that may be assigned to the Instructor for adjudication and management are set out in guidelines, [Student Course-Based Research Assignment Guidelines](http://www.queensu.ca/urs/ethics/general-research-ethics-board-greb), available on the GREB webpage at <http://www.queensu.ca/urs/ethics/general-research-ethics-board-greb> . These guidelines include:
 - The research assignment is conducted solely for pedagogical and student assessment purposes,
 - Risks to both participants and student researchers must be minimal,
 - The number of participants (or time necessary) should be minimal,

- There is no reasonable expectation of privacy attached to the data collected,
- The research data obtained and the final student research papers will not be disseminated outside of the classroom environment (or for online courses, outside of the online course's password protected domain),
- The data obtained from student course-based research projects cannot later be used for research projects involving dissemination outside of the classroom environment as secondary use of data;

5.3.7 Course-based ethics applications that meet these criteria will be given clearance and the Instructor will be delegated the responsibility of reviewing and clearing student course-based assignments;

5.3.8 Course-based ethics applications that do NOT meet these criteria must use the regular ethics application form and will be reviewed and cleared by GREB as either a delegated or full board review.

5.4 Documentation:

5.4.1 Once cleared through the delegated review process, the Ethics Coordinator will lock the ethics application and its attachments from future changes, thus maintaining a permanent record;

5.4.2 The Ethics Coordinator will prepare, on the Chair's behalf, an Ethics Clearance Letter to be issued to the researchers with its date used to calculate the one-year expiry date of GREB ethics clearance. The Ethics Clearance Letter will contain a statement that any changes to protocol, consent, etc., must be submitted as an amendment and that the ethics clearance will expire on the Ethics Clearance Letter's anniversary date, at which time an Annual

Renewal Report will need to be submitted to keep the application open;

- 5.4.3 The GREB meeting agendas and minutes will include a list of submissions that were reviewed and ethically cleared using delegated review procedures from the time that the agenda for the previous GREB meeting was issued.

6.0 REFERENCES

TCPS2 (2014) Articles 2.9, 6.12, 6.14.

7.0 APPENDICES

[Student Course-Based Research Assignment Guidelines](#)

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Review Decisions	v.402.001 2016MAR07	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 400:	Review of Research
Title:	GREB Full Board Reviews
SOP Code:	403.001
Effective Date:	2016MARCH07

Site Approvals

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

1.0 PURPOSE

This SOP describes the decisions that GREB may make during full board review of proposed research for ethical acceptability.

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.

The GREB Chair or designee is responsible for ensuring that: (1) each ethics application requiring a full board review is evaluated based on criteria set out by the TCPS2 (2014) and this SOP; (2) GREB members act with due diligence in completing the review; (3) changes needed are communicated clearly to the researchers; (4) a decision is made in a timely manner; and (5) researchers are informed of their responsibilities for the duration of the application.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Full board review is the default for new research projects submitted to GREB (Article 6.12, TCPS2 [2014]). GREB members with a Conflict of Interest (COI) in the research under review must not participate in the deliberations or in the vote of the GREB, in accordance with GREB and Queen's University Conflict of Interest (COI) policies (see SOPs 105A.001, 105B.001, 105C.001).

GREB's primary duty is to protect the rights and welfare of human research participants. However, a secondary role is to support the research enterprise by assisting researchers in fulfilling their obligations to research participants according to the TCPS2 (2014) guidelines and Queen's policies. In this capacity, GREB members endeavour to provide feedback in a positive and supportive manner, regardless of whether it is a full board or delegated review. In this spirit, GREB normally interacts with the researchers until all concerns are either addressed or justifications accepted, thus leading to ethics clearance.

5.1 Determining When a Full Board Review is Required

- 5.1.1 Full board review is the default for new research projects submitted to GREB (Article 6.12, TCPS2 [2014]).
- 5.1.2 Referral of an ethics application for a full board review may be recommended by a Unit REB, the researchers themselves, the GREB Chair or any GREB members who are in the process of reviewing a delegated review file. Full board review may also occur because of regulations such as the U.S Federalwide Assurance regulations.
- 5.1.3 The GREB Chair or designee will examine the ethics application and attachments to examine the level of risk and potential for harm based on TCPS2 (2014) definitions;
- 5.1.4 “Risk” is defined as the level of foreseeable risk posed to participants by their involvement in research. Level of risk is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties;
- 5.1.5 “Harm” is defined as any occurrence that has a negative effect on participants’ welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical, or economic;
- 5.1.6 While level of risk is the primary rationale for full board review of an ethics application, other rationale for a full board review includes concerns related to: research methods; recruitment practices; participant population; rights, safety, and well-being of research participants; confidentiality of data; and, as applicable, all regulatory and ethics guidance requirements.

5.2 Full Board Review Procedures:

- 5.2.1 The Ethics Coordinator will use the on-line Human Ethics Application System to inform the researchers if a full board review will occur at the next GREB meeting;
- 5.2.2 Prior to the meeting, all GREB members will be asked to insert their comments into the online Human Ethics Application System;
- 5.2.3 A minimum of two GREB members will be assigned to lead the discussion at the full board review meeting;
- 5.2.4 The GREB Chair will ask if anyone is in a Conflict of Interest (COI) situation with the researchers or the ethics application. If declared, the GREB member will be excused from the meeting for the duration of the discussion;
- 5.2.5 The GREB Chair will lead the discussion, summarize the main comments, and ask for consensus, if possible, or, failing consensus, a vote on whether the ethics application should be cleared or returned for clarifications/modifications;
- 5.2.6 GREB full board decisions are made by consensus, if possible, or, failing consensus, a majority vote of GREB members who are present at a GREB meeting at which there is a quorum. Quorum is defined as 50% +1 of the membership., excluding those GREB members who have recused themselves in accordance with the Conflict of interest policies;
- 5.2.7 The GREB Chair will abstain from voting except to break a tie vote or to meet quorum requirements;
- 5.2.8 GREB shall notify the researchers in writing of its decision to grant ethics clearance, require modifications/clarifications to the proposed research, or not grant ethics clearance;
- 5.2.9 If discrepancies exist among good clinical practices, statutory or regulatory requirements, and ethical considerations, GREB shall document the rationale for its decisions. The rationale shall be based on GREB's role, as described in Chapter 6 of TCPS2 (2014),

of ensuring that research complies with TCPS2 (2014) core principles as well as other applicable regulatory and ethical requirements for ensuring the protection of the rights, safety, and well-being of research participants.

5.2.10 The GREB Chair will ask GREB members if they wish to see the letter to the researchers and the researchers' response or if the review can be completed by the GREB Chair and two lead GREB reviewers;

5.2.11 Any GREB members who so desire will be included in the ongoing communications with the researchers;

5.2.12 The Ethics Coordinator will summarize the discussion at the meeting and the on-line comments in a letter form before the GREB Chair makes any necessary edits; the letter will then be sent to the two lead GREB reviewers and other interested GREB members for further review/edits; the Ethics Coordinator will then send the letter to the researchers;

5.2.13 Once the researchers respond to the letter, the GREB Chair and GREB reviewers will review the changes and request further changes, if needed;

5.2.14 This exchange process will continue until the GREB Chair and GREB reviewers feel that the TCPS2 (2014) guidelines and Queen's policies have been met;

5.2.15 Results of the clearance process will continue to remain on the GREB monthly meeting agenda until the project is cleared or not cleared;

5.2.16 If the research cannot be ethically cleared through the full board review procedures, the researcher may request that GREB reconsider its decision, followed by an appeal of the GREB decision to an independent ad hoc committee.

5.3 Ethics Clearance Granted

- 5.3.1 If the application is cleared through the full board review process, the Ethics Coordinator will lock the ethics application and its attachments from future changes, thus maintaining a permanent record;
- 5.3.2 The Ethics Coordinator will prepare, on GREB's behalf, an Ethics Clearance Letter to be issued to the researchers with its date used to calculate the one-year expiry date of GREB Ethics Clearance. The letter will inform the researchers that they must submit an annual renewal form prior to the anniversary date or ethics clearance will expire. The Ethics Clearance Letter will also contain a statement that any adverse event must be reported to GREB within 48 hours using the Serious Adverse Event form, and any changes to protocol, consent, etc., must be submitted as an amendment on an Amendment Form.

5.4 Ethics Clearance Denied

- 5.4.1 GREB may deny ethics clearance of the research when it fails to meet the ethical standards for clearance and where revision is unlikely to enable GREB to reach a positive determination;
- 5.4.2 Refusal of ethics clearance can only be decided after an initial full board review and two additional discussions after receiving the researchers' responses at subsequent GREB meetings;
- 5.4.3 The GREB Chair or designee shall ensure that the reasons for denying ethics clearance are documented in the GREB meeting minutes for communication to the researchers;
- 5.4.4 If the research is denied ethics clearance, the reasons will be communicated to the researchers in writing and the researchers will be given an opportunity to respond in person or in writing.

5.5 Reconsideration and Appeal of GREB Decisions

- 5.5.1 Researchers may appeal the decision of GREB if the disagreement between the researchers and GREB cannot be resolved through a reconsideration process at a GREB meeting at which the researchers shall have the right to speak;
- 5.5.2 Researchers must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons, and only after a final decision has been issued by GREB;
- 5.5.3 Appeals are conducted in accordance with the established GREB and Queen's University policies. GREB will ask the Vice-Principal (Research) to appoint an independent ad hoc committee that reflects a range of expertise and knowledge similar to that of GREB, and that meets the procedural requirements of this SOP;
- 5.5.4 As stated in Article 6.20 of the TCPS2 (2014), "the appeal committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final" and shall be communicated to the researchers and GREB in writing.

5.6 Documenting GREB Decisions

- 5.6.1 The GREB meeting minutes will be used to document the discussion and record all letters sent to the researchers during the full board review process;
- 5.6.2 All GREB documentation must be included in the online Human Ethics Application System. This documentation includes: (TRAQ and departmental) application number, level of review (full or delegated), date of review, reviewers' comments and researchers' responses, decision of GREB, all documents cleared for use, the

Ethics Clearance Letter with standard conditions of ethics clearance, renewal date based on the Ethics Clearance Letter, and a statement that GREB was compliant with applicable guidelines and regulations;

- 5.6.3 Upon request, GREB can provide a detailed copy of the GREB membership roster in effect on the date of GREB meeting at which the research was reviewed. A copy of the GREB membership roster, which includes name and affiliation(s), is published on the [GREB website](#).

6.0 REFERENCES

TCPS2 (2014) Articles 2.9, 6.12, 6.14, 6.18, 6.19, 6.20

7.0 APPENDICES

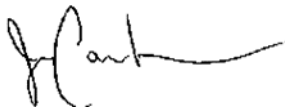
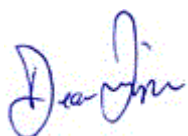
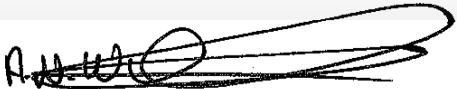
None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Full Board Reviews	v.403.001 2016MAR07	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

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

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

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). .
Initial Review - Criteria for GREB Ethical Clearance	v.404.002 2020	Updates to TCPS 2 references and terminology.

Section 400:	Review of Research
Title:	Amendments to Cleared GREB Applications
SOP Code:	405.001
Effective Date:	2016MARCH07

Site Approvals

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

1.0 PURPOSE

This SOP describes the procedures for the ongoing review activities that occur after the initial GREB Ethical Clearance of a research project and prior to the formally scheduled renewal of ethics clearance for the research project. These changes in procedures are referred to as Amendments

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

Researchers are responsible to report and gain clearance for any changes that are required throughout the course of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

TCPS2 (2014) Article 6.16 states: “Researchers shall submit to their REBs in a timely manner requests for substantive changes to their originally approved research. REBs shall decide on the ethical acceptability of those changes to the research in accordance with a proportionate approach to research ethics review”.

5.1 Amendments to Cleared Ethics Applications

5.1.1 Researchers are responsible for submitting to the GREB any changes to the ethically cleared research using the TRAQ Amendment Form with attached materials;

5.1.2 Submitted information could include:

- Modifications or changes to any previously cleared methodology or participant materials (e.g., Letter of Information/Consent Form),
- Changes in the recruitment procedures or compensation amounts,

- Changes made to protect participant privacy and confidentiality,
 - Any new procedures added to the protocol,
 - New members added to/removed from the research team,
 - Any discontinuation of the research components;
- 5.1.3 The GREB Chair or designee reviews the amendment to determine the appropriate level of GREB review required (i.e., full board or delegated review);
- 5.1.4 If the proposed change represents more than minimal risk, it should be reviewed at a GREB meeting. Amendments that might be classified as more than minimal risk would include emergency amendments that arise because of participant safety, such as:
- A change in recruitment with the potential to affect confidentiality or the perception of coercion,
 - A change in experimental procedure or research population;
- 5.1.5 If the determination is for full board review, researchers must be notified of this decision and the Ethics Coordinator or designee must place the amendment on the agenda of the next available GREB meeting;
- 5.1.6 For amendments that meet the criteria for delegated review, the Ethics Coordinator or designee will forward the Amendment Form and original application to the GREB Chair or designee;
- 5.1.7 For delegated reviews, the GREB Chair or designee will review the amendment in light of original application to determine if the amendment request falls within the purpose and procedures of the original application. If the amendment request appears to be a new or unrelated study, the GREB Chair or designee will require a new TRAQ human ethics application;
- 5.1.8 The GREB Chair or designee must decide if the changes requested are sufficiently large or significant to require the consent process to

be repeated for participants who have already participated in the research;

- 5.1.9 Modifications to the ethically cleared research may not be initiated without prior GREB review and ethical clearance except where necessary to eliminate apparent immediate hazards to participants. If changes are made to eliminate immediate hazards, researchers must notify GREB immediately.

5.2 Documenting GREB Decisions

- 5.2.1 If the amendment is cleared, the Ethics Coordinator will lock the ethics application and its attachments from future changes, thus maintaining a permanent record;
- 5.2.2 The Ethics Coordinator will prepare, on GREB's behalf, an Ethics Amendment Clearance Letter to be issued to the researchers. This letter will acknowledge the actual items cleared via the amendment request. The anniversary date of the original application will remain unchanged;
- 5.2.3 The Ethics Coordinator will prepare an Amendment Report for GREB approval at the next GREB meeting. This report will consist of: the Principal Investigator's name, the GREB file number, amendment date, title of the study, and a point-form outline of the amendment request;
- 5.2.4 GREB members are expected to identify any concerns or questions with amendments if they were initial GREB reviewers;
- 5.2.5 GREB members then vote at the GREB meeting to accept the Amendment Report.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Ongoing GREB Review Activities	v.405.001 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).

Section 400:	Review of Research
Title:	Adverse Events related to GREB Applications
SOP Code:	406.001
Effective Date:	2016APRIL01

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016April01
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016April01
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016April01
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP is one that describes the procedures for the ongoing review activities that occur after the initial GREB Ethical Clearance of a research project and prior to the formally scheduled renewal of ethics clearance for the research project. This particular SOP describes the procedures used for adverse events.

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

Researchers are responsible for reporting to GREB any new information generated throughout the course of the research that might affect the rights, safety, and well-being of research participants, including adverse events that meet the reporting criteria as outlined in this SOP and/or in the research protocol.

4.0 DEFINITIONS

An Adverse Event (AE) is defined as any event, whether or not anticipated, that adversely affects the welfare (e.g., physical, psychological, and emotional) of participants and/or researchers.

5.0 PROCEDURES

There are three sources from whom GREB could receive notice of an adverse event: (1) participants or concerned citizens, (2) researchers, and (3) the Ethics Compliance Advisor (ECA). Concerns are treated as 'Adverse Events' (until determined to be otherwise), and an investigation is opened.

5.1 Adverse Events Reported by Participants or Concerned Citizens

- 5.1.1 Participants or concerned citizens are often the initial reporter of an AE because of concern over recruitment, procedures, ethics materials (e.g., Consent Forms, survey questions) or communications;
- 5.1.2 Complaints may be verbal, by phone, email, or letter and are typically received by either the Ethics Coordinator or the GREB Chair and copied to the Ethics Compliance Advisor (ECA);

- 5.1.3 When a complaint is received, the Ethics Coordinator or Chair must get as much information as possible (e.g., nature of the complaint, dates, times, people involved and impact on the complainant). The Ethics Coordinator or Chair shall treat the complainant's personal information as confidential;
- 5.1.4 The Chair or ECA will draft a letter to the complainant re-iterating the details of the concern, asking if these details are correct and stating that GREB will launch an investigation and get back to the complainant once the investigation is concluded;
- 5.1.5 The GREB Chair or ECA will review the study file re: original ethics applications, last date of project renewal, amendments on file, and any earlier reports of adverse events. The file review could provide information that does or does not support the substance of the complaint or it might indicate other areas of concern that could require investigation;
- 5.1.6 After collecting information from the complainant and reviewing the ethics file, the Principal Investigator of the research project will be informed in writing that a complaint has been received and that it is GREB policy to consider all complaints as 'Adverse Events' until they are evaluated for merit, and, if they are evaluated for merit, how they can be resolved;
- 5.1.7 After reviewing the file and complaint, the Chair or ECA develops some questions to ask the Principal Investigator (e.g., Were they aware of the concerns? Is there merit to the concerns? How might the concerns be resolved?);
- 5.1.8 The Chair or ECA will communicate with the Principal Investigator to discuss the concerns and obtain relevant information;
- 5.1.9 After gathering information, the Chair and ECA will meet to come to a decision about the merit of the complaint (valid or invalid) and to determine how best to resolve it;

- 5.1.10 The Chair or ECA will prepare a draft letter to the Principal Investigator outlining the process, complainant's concern, results of the Chair and ECA's investigation, and required or recommended actions to be taken by the researchers to address meritorious complaints;
- 5.1.11 At the next GREB meeting, the Chair will prepare and discuss all relevant correspondence and reports and seek advice of GREB;
- 5.1.12 Based on the GREB discussion, a letter to the Principal Investigator will be prepared and sent. The letter will request feedback on the required changes by a specified date;
- 5.1.13 If further delays occur, GREB has the authority to suspend or terminate ethics clearance (see SOP 410.001 Suspension and Termination of GREB Ethical Clearance);
- 5.1.14 Once the AE has been resolved to the satisfaction of GREB, the Chair or ECA will write the complainant to discuss the merits of the original complaint and describe what changes, if any, the researchers are making to address the concerns;
- 5.1.15 If a letter of apology is to be written by the Principal Investigator to the complainant, it must first be reviewed by the GREB Chair and ECA. Since the complainant's name may be held in confidence, the GREB Chair or ECA will send the Principal Investigator's apology along with the GREB final letter.

5.2 Adverse Events Reported by the Researchers

- 5.2.1 Researchers are responsible for submitting Adverse Events to GREB on an Adverse Event Form in TRAQ;
- 5.2.2 Researchers must report to GREB any complaints they receive about concerns regarding participant rights, conflicts of interest, or other ethical issues related to the research;
- 5.2.3 Researchers must report the following to GREB:

- Any AE that, in the opinion of the researchers, meets the definitions above,
 - Any new or unexpected risk to participants' safety,
 - A change to the research that was initiated to eliminate an apparent immediate hazard,
 - Any non-compliance with an approved ethics application by members of the research team or research assistants,
 - Any breaches in confidentiality or security of the data such as: stolen computers, disclosure of Personal Information (PI), unauthorized copying, modifications or disposal of data;
- 5.2.4 Any AE involving a privacy breach must be reported to GREB and, if applicable, to the appropriate organizational official(s) within one (1) working day of researchers becoming aware of the breach;
- 5.2.5 Privacy breaches are reviewed by the GREB Chair or designee, and any recommendations including remedial actions are determined in consultation with the ECA and the Director of Research Ethics Compliance. If applicable, the Queen's University's Office of the Privacy Officer will be contacted;
- 5.2.6 All other AEs must be reported to GREB within five (5) working days of when researchers become aware of them;
- 5.2.7 Any AE reported to the GREB must have participant identifiers removed (i.e., participant code number only);
- 5.2.8 The Ethics Coordinator or designee will screen the Adverse Event Form for completeness;
- 5.2.9 The Chair and ECA will review the Adverse Event Form and seek further information from researchers as required;
- 5.2.10 The GREB Chair or designee may route the submission back to researchers to request clarifications, missing documents, or additional information;
- 5.2.11 When reviewing an AE, the Chair and ECA should:

- Assess the appropriateness of any proposed corrective actions or preventative measures by the researchers,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the researchers,
- Consider whether or not the affected research still satisfies the requirements for GREB Ethics Clearance; in particular, whether or not risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether or not some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether or not suspension or termination of the ethics clearance of the research is warranted;

5.2.12 The Chair and ECA may recommend additional remedial actions beyond the researchers' actions based on their review of the Adverse Event Form and/or communications with the researchers;

5.2.13 The GREB Chair shall add this AE to the agenda and prepare a report, if necessary. A verbal report may be adequate for AEs that were easily resolved. However, a written report should be submitted for more serious AEs or events that have not yet been resolved;

5.2.14 After the GREB meeting, the Chair will forward any further recommendations to the researchers for implementation.

5.3 Adverse Events Reported by the Ethics Compliance Advisor (ECA)

- 5.3.1 The ECA may undertake audits or site visits to follow-up on a GREB concern or spot-check various protocols and consent process;
- 5.3.2 During the natural course of this investigation, an AE may be observed;
- 5.3.3 The ECA must report this concern immediately to the GREB Chair;
- 5.3.4 Corrective action may occur, as determined by the GREB Chair in consultation with the ECA, in line with procedures outlined in Sections 5.1 and 5.2, as applicable;
- 5.3.5 As well, an Adverse Report Form must be submitted by the researchers.

5.4 Documentation of Adverse Events

- 5.3.1 Researchers are responsible for submitting an Adverse Event Form detailing the problem and the changes made to the application. If changes are made to attachments, then revised versions must be included with the file.
- 5.3.2 The Ethics Coordinator will attach to the Adverse Event Form all final copies of communications to the (anonymized) complainant, the researchers, and GREB.
- 5.3.3 The GREB minutes will be used to document the discussion and decisions made by the full board.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Adverse Events related to GREB Applications	v.406.001 2016APRIL01	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).

Section 400:	Review of Research
Title:	Renewal of Ethics Clearance
SOP Code:	407.001
Effective Date:	2016April01

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016APR01
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016APR01
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016APR01
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures and criteria for the renewal of GREB Ethics Clearance.

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

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

The GREB Chair or designee is responsible for reviewing all submitted materials for renewal of research projects.

4.0 DEFINITIONS

Suspension is defined as a temporary or permanent halt to all research activities pending future action by GREB, by the sponsor, and/or by researchers.

5.0 PROCEDURES

GREB conducts research ethics clearance renewal reviews at intervals appropriate to the degree of risk associated with the research study, but not less than once a year. Periodic review of research activities is necessary to determine if the level of risk has changed and what actions (if any) need to be taken to satisfy continued ethics clearance for the research study.

5.1 Application for Ethics Renewal

- 4.1.1 According to the TCPS2 (2014), Article 6.14, ethics clearance can be granted for only one year and must be renewed annually on or before the date of initial ethics clearance;
- 4.1.2 Researchers will be sent a courtesy reminder notice by the Ethics Coordinator of the need to submit their annual renewal form, 2-4 weeks prior to the anniversary date;
- 4.1.3 Researchers must submit an Annual Renewal Event Form available in TRAQ before the anniversary date to maintain their ethic clearance.

5.2 Renewal of Ethics Clearance by Delegated Review Procedures

- 5.2.1 When the research received initial ethics clearance via delegated review, it may undergo delegated review at the time of renewal;
- 5.2.2 Research that was previously reviewed by the full board may be assigned to delegated review at the time of renewal if conditions warrant this change;
- 5.2.3 The Ethics Coordinator or designee reviews the renewal application for completeness, including verification of the currently cleared informed Consent Form(s), and requests any clarifications, missing documents, or other information as applicable;
- 5.2.4 The Ethics Coordinator will forward the application to the GREB Chair or designee for review, if required;
- 5.2.5 The GREB Chair or designee may request additional information or clarification, as necessary, and will make a decision regarding the renewal of ethics clearance and the continued conduct of the research;
- 5.2.6 Upon reviewing the delegated renewal application, the Chair may determine that the risks are now greater than minimal and refer the application for review by the full board.

5.3 Renewal of Ethics Clearance by Full Board Procedures

- 5.3.1 Although infrequent, GREB may require researchers to submit an application for renewal of research ethics clearance at a frequency to be determined by GREB and defined at the time of the initial ethics clearance of the research, or as otherwise revised;
- 5.3.2 GREB will request and assess the renewal based on:
 - The nature of any risks posed by the research,
 - The vulnerability of the participant population,

- Whether or not the research involves novel approaches,
 - Any concerns GREB may have related to compliance or other ethical issues.
- 5.3.3 The Ethics Coordinator or designee reviews the application for completeness, and requests any clarifications, missing documents or other information from researchers, as applicable;
- 5.3.4 The Ethics Coordinator or designee will assign the application to the agenda of the next GREB meeting if the research meets the criteria for full board review;
- 5.3.5 For research that meets the criteria for full board review, GREB will discuss the research at a full board meeting and will make a decision regarding renewed ethics clearance of the research, as well as any additional determinations regarding the conduct of the research, as applicable.

5.4 GREB Documentation

- 5.4.1 To grant a renewal of the ethics clearance of the research the GREB Chair/designee or GREB must determine that:
- There have been no material changes to the research or to the informed Consent Form that have not been previously submitted and cleared,
 - There is no new Conflict of Interest or new information that has emerged that might adversely affect the safety or the well-being of research participants,
 - Risks to research participants are minimized and reasonable in relation to the anticipated benefits,
 - Informed consent processes continue to be appropriate and documented,

- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data,
- Any complaints from research participants have been followed-up appropriately;

5.4.2 GREB may also make additional determinations, including:

- Request changes to the Letter of Information and/or informed Consent Form,
- Request changes for the renewal interval (based on risks),
- Request further details, if not evident in the initial application or renewal report,
- Require justifiable modifications to the research,
- Suspend or terminate GREB Ethics Clearance.

5.5 Renewal Applications not Received by the Expiry Date

5.5.1 The Principal Investigator or designee is responsible for maintaining GREB Ethics Clearance for active studies. As per TCPS2 (2014) and in accordance with GREB SOPs, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study;

5.5.2 If an application for renewal is not submitted before the expiry date, then a letter (Suspension of Ethics Clearance) will be sent to the Principal Investigator by the Chair or designee advising the Principal Investigator that their ethics clearance has been suspended;

5.5.3 When ethics compliance is suspended, the Principal Investigator must cease all research activities. If, however, the safety, rights, and well-being of participants would be in jeopardy due to a suspension of research activity, then the Principal Investigator is

responsible for contacting GREB immediately to ask for a postponement of the suspension until the renewal form can be submitted;

- 5.5.4 In the event of a suspension in ethics clearance, the Principal Investigator or designee will be responsible for notifying GREB if there is a desire to continue the research project;
- 5.5.5 The Principal Investigator or designee must document the reasons for allowing the research ethics clearance to lapse on the renewal form and identify the steps taken to prevent future suspensions;
- 5.5.6 If the research study has been discontinued, then it is the responsibility of the Principal Investigator or designee to inform GREB of the discontinuation;
- 5.5.7 In the renewal form, the Principal Investigator or designee should provide as much detail as possible about the proposed continued activities. The GREB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the Principal Investigator or designee, if required;
- 5.5.8 The Principal Investigator may resume research activities once ethics clearance of the research has been issued;
- 5.5.9 The suspension in ethics clearance will be documented on the renewal letter issued by GREB;
- 5.5.10 GREB may refuse to review new research submissions until suspensions in ethics clearance have been resolved for any ongoing research projects;
- 5.5.11 If, after the Ethics Office has tried to contact the Principal Investigator and GREB has still not received any response from the Principal Investigator in a timely manner, then the Chair may request GREB to terminate the ethics clearance;
- 5.5.12 When an ethics application is terminated, the Chair or designee will send the Principal Investigator a termination letter;

5.5.13 Once an ethics application has been terminated, a new ethics application will be required for the study if the Principal Investigator wishes to re-activate the study.

6.0 REFERENCES

[TCPS2 \(2014\), Article 6.14](#)

7.0 APPENDICES

1. Ethics Coordinator Courtesy Reminder Letter Template
2. Chair Suspension Letter to Principal Investigator Template
3. Chair Letter of Termination Template

8.0 REVISION HISTORY

SOP Title	Version	Updates
Renewal of Ethics Clearance	v.407.001 2016APR01	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).

Appendix 1

ETHICS COORDINATOR COURTESY REMINDER LETTER

Dear [[PrincipalInvestigatorSalutation]]:

RE: [[ProjectTitle]]

File# [[FileNo]]

According to our records, the above-noted protocol is due for annual renewal on **[[RenewalDue]]**. Please login to the **TRAQ Researcher Portal** to complete, and submit, the *GREB Annual Renewal Form for Approved Studies*. **If your project is complete or abandoned, you still need to submit this form for GREB review.**

The Principal Investigator is responsible for maintaining GREB Ethical Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's SOP 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study.

In the event that an Annual Renewal Report is not submitted for review before the expiry date, ethics clearance will be suspended for your study the day after your ethics clearance expires, at which point, any further research activity must be discontinued. In the event of a suspended ethics clearance, the Principal Investigator must contact GREB. As a result of a suspension, the Annual Renewal Report may go to a full board review. The Principal Investigator must document the reasons for the suspension and identify the steps taken to prevent future suspensions. If GREB does not hear from the Principal Investigator or designee in a timely manner, the study will be terminated (see GREB's SOP 407.001 GREB Renewal of Ethics Clearance and 410.001 Suspension and Termination of GREB Ethical Clearance).

How to Submit a Renewal Form:

1. Visit https://eservices.queensu.ca/romeo_researcher/ if you use SSO (Single Sign On) or https://eservices.queensu.ca/romeo_researcher_admin/ if you use your full email address* as Username
2. Sign on with your Queen's Net ID (or full email address*) and password
3. Click 'My Reminders' or 'Applications (Submitted-Post Review)'
4. Click the 'EVENTS' link next to the file no **[[FileNo]]**.
5. Select the form titled *GREB Annual Renewal Form for Approved Studies* by clicking on its hyperlink under "New Event Forms" section.
6. Complete all fields.
7. Save.
8. Submit.

Sincerely,

Gail Irving
Ethics Coordinator
General Research Ethics Board
University Research Services

Room 302C, Fleming Hall/Jemmett Wing
Queen's University

Note: Instructional video: "Submitting and Tracking Event Forms" can be found at:
<http://www.youtube.com/watch?v=IVH7t9ezZIk>

Instructional video: "General Research Ethics Board (GREB) - Event Forms" can be found at:
<http://www.youtube.com/watch?v=sVSBNPVeVzo>

Appendix 2

CHAIR - SUSPENDED ANNUAL RENEWAL EMAIL

[[Today]]

Dear [[PrincipalInvestigatorLongName]],

Re: Study Title: "[[ProjectTitle]]

ROMEO File No. [[FileNo]]

According to our records, the above-noted research study was due for annual renewal on [[RenewalDue]] and is now past due. **Your GREB research ethics clearance is now suspended. All research activity under this ethics application must be stopped.** Failure to respond to this notice will result in termination of your research ethics clearance.

The Principal Investigator is responsible for maintaining GREB Ethics Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's SOP 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study.

In the event that an Annual Renewal Report is not submitted for review before the expiry date, ethics clearance will be suspended for your study the day after your ethics clearance expires, at which point, any further research activity must be discontinued. In the event of a suspended ethics clearance, the Principal Investigator must contact GREB. As a result of a suspension, the Annual Renewal Report may go to a full board review. The Principal Investigator must document the reasons for the suspension and identify the steps taken to prevent future suspensions in the renewal form in TRAQ. If GREB does not hear from the Principal Investigator or designee in a timely manner, ethics clearance for the study will be terminated (see GREB's SOP 407.001 GREB Renewal of Ethics Clearance and 410.001 Suspension and Termination of GREB Ethical Clearance).

Sincerely,

[[UserLongName]]

GREB Chair

University Research Services

Fleming Hall-Jemmett Wing, 3rd Floor

78 Fifth Field Company Lane

Queen's University

Kingston, ON K7L 3N6

Tel: (613) 533-6081 ext 78281

chair.GREB@queensu.ca

Appendix 3

CHAIR – GREB TERMINATION OF ETHICS CLEARANCE

[[Today]]

Dear [[PrincipalInvestigatorLongName]] ,

Re: Study Title: "[[ProjectTitle]]"

ROMEO File No. [[FileNo]]

According to our records, the above-noted research study was due for annual renewal on [[RenewalDue]] and is now past due.

The Principal Investigator is responsible for maintaining GREB Ethics Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's Standard Operating Procedures (SOPs) 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from the GREB must be renewed at least once per year.

Attempts to contact you have failed. This letter is to advise you that your research study's ethics clearance has been terminated (see GREB's SOP 410.001 Suspension and Termination of GREB Ethical Clearance).

Sincerely,

[[UserLongName]]

GREB Chair

University Research Services

Fleming Hall-Jemmett Wing, 3rd Floor

78 Fifth Field Company Lane

Queen's University

Kingston, ON K7L 3N6

Tel: (613) 533-6081 ext 78281

chair.GREB@queensu.ca

Section 400:	Review of Research
Title:	Research Completion
SOP Code:	408.001
Effective Date:	2016MARCH07

Site Approvals

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

1.0 PURPOSE

This SOP describes the procedures for the closure of research with the GREB.

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.

The GREB Chair or designee is responsible for determining if any of the submitted materials should be reviewed by the Full Board.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Completion of Research is a change in activity that must be reported to GREB. A Final Report allows GREB to close its files in addition to providing the GREB with information that may be used in the evaluation and ethical clearance of related studies.

5.1 Determining when Research can be Closed

- 5.1.1 Researchers may submit a Renewal Form using the TRAQ Researcher Portal to report when there is no further participant involvement at the site, all new data collection is complete;
- 5.1.2 GREB recommends that all studies remain open until a manuscript has been accepted for publication (if applicable) in the event that further follow-up with respect to data collection is required;
- 5.1.3 The Ethics Coordinator or designee will review the Renewal Form and request any outstanding information, clarification, or documentation from the researchers, if needed;
- 5.1.4 The GREB Chair or designee will review the submission and issue a Letter of Acknowledgement (if applicable) to the researchers. The research status in TRAQ will change to “Closed”;

- 5.1.5 Once a research project is “Closed” with GREB, no further submissions for that research will be permitted; however, if required, researchers may still “clone” the application;
- 5.1.6 If there are exceptional circumstances, a request to re-open the research file shall be made to GREB and the conditions of this request will be determined at the time of the review.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Research Completion	v.408.001 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).

Section 400:	Review of Research
Title:	Research Requiring Federalwide Assurance (FWA)
SOP Code:	409.001
Effective Date:	2016March07

Site Approvals

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

1.0 PURPOSE

This SOP pertains to GREB and its authority to review and approve human participant research in compliance with applicable United States (US) Federalwide Assurance (FWA) of Protection for Human Subjects regulations, policies, and current and emerging best practices.

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. Researchers are responsible for complying with FWA regulations when receiving funding from any US federal department or agency that has adopted the Common Rule.

The Ethics Compliance Advisor (ECA) is responsible for ensuring that all updates and renewals are reported to the US Office of Human Research Protection (OHRP).

4.0 DEFINITIONS

“Federally supported” is defined in this SOP and in the FWA as the US Government providing any funding or other support (including, but not limited to, providing supplies, products, drugs, and identifiable private information collected for research purposes) and/or the conduct of the research involves US Government employees.

FWA Adverse Event ([FWA]AE) is defined in this SOP as “any untoward or unfavorable occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events encompass both physical and psychological harms.”¹

5.0 PROCEDURES

All research engaged in US federally supported human participant research, which is not otherwise exempt from the Federal Policy for the Protection of Human Subjects,

¹ Although the HHS regulations do not define or use the word adverse event, this is the common definition of this term across government and non-government entities modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practices. (See <http://www.hhs.gov/ohrp/policy/advevntguid.html>)

must comply with the US Federal Policy for the Protection of Human Subjects, known as the Common Rule. All US federally supported human participant research must also comply with any additional human participant regulations, policies, and current and emerging best practices. All human participant research conducted or supported by the US Department of Health and Human Services (DHHS) must comply with all subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D).

The US Federal Office for Human Research Protections (OHRP) requires that (US) federally supported (i.e., conducted or supported) research involving human participants only be conducted at facilities covered by a Federalwide Assurance (FWA). Through the FWA, GREB commits to the Department of Human Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

- Queens' University FWA number is: **FWA00004184**
- Queens' University GREB IRB number is: **IRB00003062**

5.1 Update or Renewal of Institutional Review Board (IRB) Registration

- 5.1.1 IRB registration update must be made within 90 days after changes regarding the contact person (i.e., the ECA) who provided the IRB registration information, the GREB Chair, or GREB membership;
- 5.1.2 If Queens' University decides to disband a registered IRB that it is operating, it must be reported in writing within 30 days after permanent cessation of the IRB's review of US Department of Health and Human Services (HHS) conducted or supported research;
- 5.1.3 IRB Registration is effective for 3 years and must be renewed every 3 years, even if no changes have occurred, to maintain an active FWA. Any renewal or update that is submitted electronically and

approved by US Office for Human Research Protections (OHRP) begins a new 3-year effective period.

5.2 Federalwide Assurance (FWA) Clearance

- 5.2.1 Except for research exempted or waived in accordance with Sections 101(b) or 101(i) of the Common Rule, all US federally supported human participant research will be reviewed, prospectively approved, and subject to continuing oversight and review (depending on the degree of risk) at least annually by GREB;
- 5.2.2 GREB Members should identify and bring to the attention of the GREB Chair, Ethics Coordinator, or the Ethics Compliance Advisor (ECA) ethics applications that receive US government funding or that identify the study as requiring Federalwide Assurance (FWA) compliance. The Chair or ECA will determine if the research study and ethics application meet the criteria for ethics clearance according to FWA regulations, policies, and current and emerging best practices;
- 5.2.3 For FWA clearance, the typical GREB clearance steps must be followed, namely: a completed submission and reviewed by GREB delegated or full board review. GREB and/or GREB Office Personnel may consult researchers for additional information as necessary (see SOP 402.001 GREB Delegated Review or 403.001 GREB Full Board Review);
- 5.2.4 Following initial review of the research, the GREB shall make a determination as to the compliance of the research with FWA and communicate this determination to OHRP;
- 5.2.5 Participant recruitment/registration, pilot studies, obtaining informed consent, access or collection of data and collection of data cannot start prior to receiving written ethical clearance by GREB and FWA.

- 5.2.6 In addition to GREB and FWA Ethics Clearance, the requirements of where the research will be conducted must be met before the research can begin (e.g., department approvals, adequate resources);
- 5.2.7 In accordance with FWA regulations, policies, and current and emerging best practices, researchers shall report to GREB any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants, any unanticipated events, and any serious or continuing non-compliance, including reportable events that meet the reporting criteria as outlined in this SOP and/or in the research protocol;
- 5.2.8 Unexpected Adverse Event Reports² must be reported to US Office for Human Research Protections (OHRP) according to the required time-line for reporting incidents (see “Guidance on Reporting Incidents to OHRP” - <http://www.hhs.gov/ohrp/compliance/reports/index.html>). Incident reports include reports of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance, the requirements or determinations of the GREB, and suspension or termination of GREB approval;
- 5.2.9 GREB will have authority to approve, suspend, terminate, require modifications in, or, where it deems the risks to participants exceeds the benefits of the research, not grant ethical clearance.

² See U.S. Department of health and Human Sciences (HHS) “Unanticipated Problems Involving Risks and Adverse Events Guidance” (2007) - <http://www.hhs.gov/ohrp/policy/advevntguid.html> (accessed 2016FEB29)

5.3 Update of Renewal of Federalwide Assurance (FWA)

- 5.3.1 Each institution must complete and submit its FWA updates and renewals using the electronic submission system available through the OHRP Web site at <http://ohrp.cit.nih.gov/efile/>;
- 5.3.2 The FWA Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally-binding agreement;
- 5.3.3 Incident reports, which include reports of unanticipated problems involving risks to participants or others; Serious Adverse Events³, serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of GREB; and suspension or termination of GREB clearance of a research study must be reported to OHRP. See Guidance on Reporting Incidents to OHRP at: <http://www.hhs.gov/ohrp/compliance/reports/index.html>;
- 5.3.4 Renewal/update is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, to maintain an active FWA. Any renewal or update that is submitted electronically and approved by US Office for Human Research Protections (OHRP) begins a new 5-year effective period.

5.4 Non-exemptions from FWA Compliance

- 5.4.1 Research that is not exempt from FWA Compliance:
 - Intervenes or interacts with human participants for purposes of US federally-supported research,

³ U.S. FDA defines a Serious Adverse Event as any undesirable experience associated with the use of a medical product in a patient [or participation in research – my brackets] that results in the following outcomes: death, life threatening experience, hospitalization (initial or prolonged), disability of permanent damage (i.e., substantial disruption of a person's ability to conduct normal life functions), congenital anomaly/birth defect, or other serious medical outcomes. See <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm> (accessed 2016FEB29)

- Obtains individually identifiable private information about human participants for purposes of US federally-supported research, or
- Receives a direct US federal award to conduct human participant research, even where a subcontractor or collaborator carries out all activities involving human participants.

6.0 REFERENCES

US Federal Policy for the Protection of Human Subjects, known as The Common Rule; and all subparts of DHHS Regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its subparts A, B, C, and D).

U.S. Department of health and Human Sciences (HHS) “Unanticipated Problems Involving Risks and Adverse Events Guidance” (2007) -

<http://www.hhs.gov/ohrp/policy/advevntguid.html> (accessed 2016FEB29)

HHS, “Guidance on Reporting Incidents to OHRP” (2011) -

<http://www.hhs.gov/ohrp/compliance/reports/index.html> (accessed 2016FEB29)

7.0 APPENDICES

1. [OHRP Guidance on Reporting Incidents](#)

8.0 REVISION HISTORY

SOP Title	Version	Updates
Research Requiring Federalwide Assurance (FWA)	v.409.001 2016MAR07	Original: This SOP was developed based on information from the US Federalwide Assurance (FWA) documents, and the US Office for Human Research Protections (OHRP) documents as well as Queen's University previous documents or policies (using the format of CAREB/N2).

Section 400:	Review of Research
Title:	Suspension or Termination of GREB Ethics Clearance
SOP Code:	410.001
Effective Date:	2016APRIL01

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016APR01
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016APR01
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016APR01
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures associated with the suspension or termination of GREB Ethics Clearance of research.

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 is responsible for determining whether or not any information received throughout the course of the research requires the suspension or termination of GREB Ethical Clearance.

Researchers are responsible for notifying GREB and Queen's University officials (if applicable) if their research is abandoned or completed, or if ethics clearance is suspended or terminated by another REB (in the case of multijurisdictional studies) or by a regulatory agency. They need to provide a detailed explanation for the action.

4.0 DEFINITIONS

Suspension is defined as a temporary or permanent halt to all research activities pending future action by GREB, by the sponsor and/or by researchers.

Termination is defined as a permanent halt by GREB, by the sponsor, and/or by researchers to all or some research activities.

5.0 PROCEDURES

As a result of ongoing review activities, GREB may require that research be modified, or may suspend or terminate GREB Ethics Clearance if the risks to the research participants are determined to be unreasonably high; for example, cases in which there are high numbers of Serious Adverse Events or when there is evidence that researchers are not conducting the research in compliance with applicable regulations and guidelines. GREB also has the authority to suspend new enrollment while additional information is being requested.

A decision to suspend or to terminate GREB's Ethics Clearance of the research must include consideration of the safety, rights, and well-being of the participants already

enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

Researchers may decide to voluntarily suspend or terminate some or all research activities; however, this action is not considered a suspension or termination of GREB Ethics Clearance.

5.1 Suspension or Termination of GREB Ethics Clearance

5.1.1 If any concerns are raised during GREB's oversight of research that are related to new information or to the conduct of the research, GREB may suspend or terminate ethics clearance of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with GREB cleared protocol or GREB requirements,
- The research is associated with unexpected serious harm to participants (as may be determined following GREB review of reportable events),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by GREB (e.g., under a suspension or ethics clearance with modifications),
- Repeated or deliberate failure to properly obtain or document consent from research participants,
- Repeated or deliberate failure to comply with conditions placed on the research by GREB or by regulatory agencies,
- Repeated or deliberate failure to obtain prior GREB review and ethics clearance of amendments or modifications to the research, or

- Repeated or deliberate failure to maintain accurate research records or submit required reportable adverse events to GREB;
- 5.1.2 The GREB Chair or designee is authorized to suspend GREB Ethics Clearance of research; however, the GREB Chair or designee is not authorized to terminate GREB Ethics Clearance. If the Chair or designee suspends ethics clearance of the research, he or she must notify GREB of this suspension at its next GREB meeting;
- 5.1.3 GREB is authorized to terminate ethics clearance of the research following a review at a GREB meeting;
- 5.1.4 Prior to suspending or terminating GREB Ethical Clearance, GREB must consider:
- Risks to current participants,
 - Actions to protect the safety, rights, and well-being of currently enrolled participants,
 - The appropriate care and monitoring of research participants,
 - Whether or not withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
 - Whether or not participants should be informed of the termination or suspension,
 - Identification of a time frame during which corrective measures are to be implemented;
- 5.1.5 If GREB Ethics Clearance is suspended or terminated, the GREB Chair or designee will issue a formal letter to the researchers with the reasons for GREB action and the corrective measures required by GREB;

- 5.1.6 Unless otherwise stated by GREB, when the GREB Chair or designee suspends ethics clearance, no further research activities can take place other than the submission of event forms;
- 5.1.7 If GREB Ethical Clearance has been suspended, the suspension may be lifted after corrective actions are completed to GREB's satisfaction.
- 5.1.8 Upon termination of ethics clearance by the GREB, if the researchers wish to re-activate the research study, they will be required to resubmit a new ethics application to GREB.

5.2 Reporting Suspensions or Terminations

- 5.2.1 The GREB Chair or designee will report any suspension or termination of GREB Ethics Clearance to appropriate officials at Queen's University and has the authority to notify the regulatory authorities (as applicable). GREB may delegate regulatory authority reporting as applicable.

6.0 REFERENCES

TCPS2 (2014), [Article 6.3](#) and [Article 6.14](#)

7.0 APPENDICES

1. Ethics Coordinator Courtesy Reminder Letter Template
2. Chair Suspension Letter to Principal Investigator Template
3. Chair Letter of Termination Template

8.0 REVISION HISTORY

SOP Title	Version	Updates
Suspension or Termination of GREB Ethical Clearance	v.410.001 2016APRIL01	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).

Appendix 1

ETHICS COORDINATOR COURTESY REMINDER LETTER

Dear [[PrincipalInvestigatorSalutation]]:

RE: [[ProjectTitle]]

File# [[FileNo]]

According to our records, the above-noted protocol is due for annual renewal on **[[RenewalDue]]**. Please login to the **TRAQ Researcher Portal** to complete, and submit, the *GREB Annual Renewal Form for Approved Studies*. **If your project is complete or abandoned, you still need to submit this form for GREB review.**

The Principal Investigator is responsible for maintaining GREB Ethical Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's SOP 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study.

In the event that an Annual Renewal Report is not submitted for review before the expiry date, ethics clearance will be suspended for your study the day after your ethics clearance expires, at which point, any further research activity must be discontinued. In the event of a suspended ethics clearance, the Principal Investigator must contact GREB. As a result of a suspension, the Annual Renewal Report may go to a full board review. The Principal Investigator must document the reasons for the suspension and identify the steps taken to prevent future suspensions. If GREB does not hear from the Principal Investigator or designee in a timely manner, the study will be terminated (see GREB's SOP 407.001 GREB Renewal of Ethics Clearance and 410.001 Suspension and Termination of GREB Ethical Clearance).

How to Submit a Renewal Form:

1. Visit https://eservices.queensu.ca/romeo_researcher/ if you use SSO (Single Sign On) or https://eservices.queensu.ca/romeo_researcher_admin/ if you use your full email address* as Username
2. Sign on with your Queen's Net ID (or full email address*) and password
3. Click 'My Reminders' or 'Applications (Submitted-Post Review)'
4. Click the 'EVENTS' link next to the file no **[[FileNo]]**.
5. Select the form titled *GREB Annual Renewal Form for Approved Studies* by clicking on its hyperlink under "New Event Forms" section.
6. Complete all fields.
7. Save.
8. Submit.

Sincerely,

Gail Irving
Ethics Coordinator
General Research Ethics Board
University Research Services

Room 302C, Fleming Hall/Jemmett Wing
Queen's University

Note: Instructional video: "Submitting and Tracking Event Forms" can be found at:
<http://www.youtube.com/watch?v=IVH7t9ezZIk>

Instructional video: "General Research Ethics Board (GREB) - Event Forms" can be found at:
<http://www.youtube.com/watch?v=sVSBNPVeVzo>

Appendix 2

CHAIR - SUSPENDED ANNUAL RENEWAL EMAIL

[[Today]]

Dear [[PrincipalInvestigatorLongName]],

Re: Study Title: "[[ProjectTitle]]"
ROMEO File No. [[FileNo]]

According to our records, the above-noted research study was due for annual renewal on [[RenewalDue]] and is now past due. **Your GREB research ethics clearance is now suspended. All research activity under this ethics application must be stopped.** Failure to respond to this notice will result in termination of your research ethics clearance.

The Principal Investigator is responsible for maintaining GREB Ethics Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's SOP 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from GREB must be renewed at least once per year. It is at the discretion of GREB to require renewals more often, if need be, appropriate to the degree of risk within the study.

In the event that an Annual Renewal Report is not submitted for review before the expiry date, ethics clearance will be suspended for your study the day after your ethics clearance expires, at which point, any further research activity must be discontinued. In the event of a suspended ethics clearance, the Principal Investigator must contact GREB. As a result of a suspension, the Annual Renewal Report may go to a full board review. The Principal Investigator must document the reasons for the suspension and identify the steps taken to prevent future suspensions in the renewal form in TRAQ. If GREB does not hear from the Principal Investigator or designee in a timely manner, ethics clearance for the study will be terminated (see GREB's SOP 407.001 GREB Renewal of Ethics Clearance and 410.001 Suspension and Termination of GREB Ethical Clearance).

Sincerely,

[[UserLongName]]
GREB Chair
University Research Services
Fleming Hall-Jemmett Wing, 3rd Floor
78 Fifth Field Company Lane
Queen's University
Kingston, ON K7L 3N6
Tel: (613) 533-6081 ext 78281
chair.GREB@queensu.ca

Appendix 3

CHAIR – GREB TERMINATION OF ETHICS CLEARANCE

[[Today]]

Dear [[PrincipalInvestigatorLongName]] ,

Re: Study Title: "[[ProjectTitle]]"

ROMEO File No. [[FileNo]]

According to our records, the above-noted research study was due for annual renewal on [[RenewalDue]] and is now past due.

The Principal Investigator is responsible for maintaining GREB Ethics Clearance for active research studies involving human participants. As per the TCPS2 (2014), GREB's Standard Operating Procedures (SOPs) 407.001 GREB Renewal of Ethics Clearance, and in accordance with current best practices, studies with ethics clearance from the GREB must be renewed at least once per year.

Attempts to contact you have failed. This letter is to advise you that your research study's ethics clearance has been terminated (see GREB's SOP 410.001 Suspension and Termination of GREB Ethical Clearance).

Sincerely,

[[UserLongName]]

GREB Chair

University Research Services

Fleming Hall-Jemmett Wing, 3rd Floor

78 Fifth Field Company Lane

Queen's University

Kingston, ON K7L 3N6

Tel: (613) 533-6081 ext 78281

chair.GREB@queensu.ca

Section 500:	Reviews Requiring Special Consideration
Title:	GREB Review during Publicly Declared Emergencies
SOP Code:	501.001
Effective Date:	2016March30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the research ethics review procedures during publicly declared emergencies.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

A publicly declared emergency is an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official in accordance with legislation and/or public policy. Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses. Examples include natural disasters, large communicable disease outbreaks, environmental disasters, and humanitarian emergencies. Such emergencies may represent significant risks for research participants in ongoing research or in new research initiated as a result of the emergency. They tend to be time-limited. Special care should be given to request for exceptions to the ordinary system for obtaining REB approval for research, as potential research participants who may not normally be considered vulnerable may become so by the very nature of the public emergencies, while those already vulnerable may become acutely so.

During publicly declared emergencies, GREB follows established procedures to continue to provide the necessary research ethics oversight. Research ethics review during publicly declared emergencies may necessitate the use of innovative practices. Depending upon the nature of the emergency, for example, GREB may not be able to meet in person, and delegated review procedures may have to be designed to respond to either urgent opportunities for new research or to current ongoing research; however, the existence of an emergency does not override established procedures to protect the welfare of research participants. Any relaxation of the usual procedural requirements for

review should be proportionate to the complexity and urgency of the emergency, as well as to the risks posed by the research under review. Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified, and should cease as soon as possible after the emergency ends.

5.1 Determining the Level of Impact

- 5.1.1 Subsequent to an officially publicly declared emergency, the GREB Chair or designee will assess the level of impact on the research ethics review processes;
- 5.1.2 There are three levels of impact that may influence how ethics review will be conducted during the publicly declared emergency:
 - Mild – little or no impact,
 - Moderate – some impact; decisions to proceed at the discretion of the Chair or designee, in consultation with researchers, as necessary,
 - Severe – extremely debilitating to normal research ethics review procedures; decisions to proceed at the discretion of the Chair or designee;
- 5.1.3 The GREB Chair or designee will use the level of impact to guide the review of research submissions during the publicly declared emergency;
- 5.1.4 Pending the determination of the level of impact on the review of ongoing or new research, the currently established ethics review procedures should be followed.

5.2 Emergency Preparedness Procedures

- 5.2.1 Subsequent to an officially publicly declared emergency, temporary ethics review processes may be instituted;
- 5.2.2 When the impact on the ethics review processes is deemed to be severe, teleconferences or videoconferences may be used to conduct GREB meetings;
- 5.2.3 When the impact on the ethics review processes is deemed to be severe, GREB office personnel may conduct their activities remotely if possible and practical;
- 5.2.4 The GREB Chair or designee may suspend the currently established GREB meeting quorum, in which case a GREB subcommittee would be established for the duration of the publicly declared emergency;
- 5.2.5 The GREB subcommittee composition should be in accordance with the standard GREB membership requirements and should include at least five members drawn from the existing GREB membership;
- 5.2.6 The current GREB Chair or designee should serve as the Chair of the GREB subcommittee;
- 5.2.7 At his/her discretion, the GREB Chair or designee may invite individuals with expertise in special areas to assist in the review of issues that require expertise beyond that available to the GREB subcommittee; however, ad hoc advisors may not contribute directly to the subcommittee's decisions and their presence shall not be used in establishing a quorum;
- 5.2.8 When the impact is deemed to be severe, the GREB Chair or designee may refer the ethics review and research oversight of new and ongoing research to another REB (at or outside of the institution), subject to the applicable regulations and agreements;
- 5.2.9 Where research submissions are deemed to be more than minimal risk and subject to applicable regulations, the GREB Chair or

designee will use his/her judgment in determining the type of review required (delegated or full board), taking into account the severity of the impact of the emergency and the complexity and urgency of the submission;

- 5.2.10 Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency must be documented and appropriately justified;
- 5.2.11 The GREB Chair or designee should periodically assess the impact of the emergency on the ethics review processes and adjust any temporary ethics review processes accordingly;
- 5.2.12 Any modifications that are made in the application of research ethics policies and procedures during a publicly declared emergency will cease as soon as is feasible after the emergency has officially ended (i.e., as declared by an authorized public official). The GREB Chair or designee will determine when to resume routine ethics review processes;
- 5.2.13 All delegated ethical clearances of research following a publicly declared emergency must be assessed to determine if subsequent full board review is required at the first opportunity subsequent to the cessation of the publicly declared emergency;
- 5.2.14 At the conclusion of the publically declared emergency, the GREB Chair or designee and GREB office personnel should work with GREB subcommittee members to evaluate the effectiveness of GREB's declared emergency procedures and to make recommendations for improvements.

5.3 Review of Ongoing Research NOT Related to or Arising from the Publicly Declared Emergency

5.3.1 When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the following will apply to the review of ongoing research:

- The GREB Chair or designee will determine if the research needs to continue, or if it can be suspended until after the emergency is over,
- The research may continue at the discretion of the GREB Chair or designee in consultation with researchers, as necessary,
- Researchers' responses to GREB reviews, major amendments, and adverse events will be prioritized for review,
- Renewals will receive the next priority for review, followed by research completion reports,
- Other submissions will be reviewed as time allows;

5.3.2 When the impact of the publicly declared emergency on ethics review is determined to be severe, the following will apply to the review of ongoing research:

- Research activities not involving, or no longer involving, recruitment or direct contact with participants may continue,
- Research activities involving recruitment or direct contact with participants may only continue if ceasing such activity might pose significant risks to participant safety,
- Major amendments and adverse events related to these studies will be reviewed by the GREB subcommittee or the GREB Chair or designee, as appropriate.

5.4 Review of NEW Research NOT Related to or Arising from the Publicly Declared Emergency

- 5.4.1 When the impact of the publicly declared emergency on ethics review is determined to be mild to moderate, the GREB Chair or designee will determine whether review of any new research not related to the publicly declared emergency may proceed or will be postponed until after the emergency is over;
- 5.4.2 When the impact of the publicly declared emergency on ethics review processes is determined to be severe, any new research not related to the publicly declared emergency will not be reviewed until the emergency is declared to be over.

5.5 Review of Research RELATED to or Arising from the Publicly Declared Emergency

- 5.5.1 If a request to review research related to a publicly declared emergency is received, it will be directed to the GREB Chair or designee, as applicable;
- 5.5.2 The GREB Chair or designee will assess the risks associated with the proposed research, as well as aspects of the research that might require enhanced scrutiny or diligence, taking into account the severity of the impact of the emergency on ethics review processes;
- 5.5.3 When the impact of the publicly declared emergency on ethics reviews is determined to be mild to moderate, research related to the publicly declared emergency has priority for review;
- 5.5.4 When the impact of the publicly declared emergency on ethics review is determined to be severe, time-sensitive review processes may be followed, such as delegated review as appropriate, review by a GREB subcommittee, and/or meetings conducted via teleconference or videoconference, should be put into place.

6.0 REFERENCES

TCPS2 (2014), [Chapter 3, Article 3.7](#); and [Chapter 6, Section D](#).

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
GREB Review during Publicly Declared Emergencies	v.501.001 2016MARCH30	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Section 600:	GREB Communication and Notification
Title:	Communication – Researcher
SOP Code:	601.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes GREB communication with researchers and with research teams.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

In the interest of enhancing human research participant protection, it is important for GREB to foster collaboration and open communication between and among GREB, researchers, research staff, and Queen's University representatives. This mandate extends not only to communication related to a specific research project, but also to communication related to ethical issues and GREB processes, policies, and procedures.

To facilitate clear and accurate communication with researchers and research staff, GREB will follow standardized notification and documentation procedures. Researchers participating in GREB-cleared research shall be informed, in writing, of all determinations made by GREB regarding specific research. Feedback from researchers should be encouraged and be considered as an opportunity to review and improve the function of GREB and GREB office procedures.

5.1 Notification of GREB Decisions

- 5.1.1 GREB will notify researcher and research teams of GREB's decision following the review (i.e., from the full board or delegated review date) of new research, modifications, or amendments to currently ethically cleared research, applications for renewal, and reportable events;

- 5.1.2 The determinations of GREB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the submission not being cleared (when appropriate);
- 5.1.3 If the research does not receive initial ethics clearance or is not cleared for renewal of ethics clearance, the Ethics Coordinator will notify researchers of GREB's decision by formal written notification;
- 5.1.4 The GREB Chair or designee will review the draft GREB Review Letter, make revisions as necessary, and indicate his/her approval;
- 5.1.5 The GREB Review Letter will be issued to the researchers;
- 5.1.6 Researchers will be asked to include the GREB ROMEO number assigned to the research in all subsequent correspondence with GREB;
- 5.1.7 Upon receipt of the researchers' response to the GREB Review Letter, GREB will follow-up with researchers and their research staff to request any additional clarifications as requested by the GREB Chair or designee, or the reviewers;
- 5.1.8 Once all of the GREB conditions are satisfied, the Ethics Coordinator or designee will issue an Ethical Clearance Letter on behalf of GREB.

5.2 Research Appeal of GREB Decision

- 5.2.1 Researchers may request a reconsideration or appeal of the decision of GREB and of any revisions to the research requested by GREB;
- 5.2.2 The appeal process is outlined in SOP 402.001, GREB Review Decisions and is conducted in accordance with established Queen's University policies and procedures;

5.2.3 Only GREB full board review may lift a restriction or re-review previous research that was not granted ethics clearance. Delegated review procedures may not be used.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Communication – Researcher	v.601.001 2016MAR30	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Section 600:	GREB Communication and Notification
Title:	Communication – Research Participants
SOP Code:	602.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the process for GREB communication with research participants.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Research participants should be able to voice in confidence their concerns and questions and request information regarding their participation or potential participation in research to an informed individual on GREB or in the GREB office.

5.1 Communication with Research Participants

- 5.1.1 Research participants are encouraged to contact (by telephone or in writing) the GREB office with questions and concerns, using the contact information provided in the informed consent document. If requested, the identity of the participants will not be recorded or shared;
- 5.1.2 GREB office personnel must document all communication with research participants;
- 5.1.3 When concerns are received by either the Ethics Coordinator or the GREB Chair, they will decide if these complaints warrant greater review and the involvement of either the Ethics Compliance Advisor or Director of Research Ethics Compliance;
- 5.1.4 The GREB Chair or designee may choose to involve the Ethics Compliance Advisor and/or Director of Research Ethics Compliance to work to resolve participant issues through

mechanisms, such as a follow-up with researchers, other Queen's University representatives, and appropriate federal agencies, as applicable;

5.1.5 The GREB Chair or designee documents all communication with research participants and a de-identified record of this communication is maintained securely in the research file;

5.1.6 If applicable, GREB members will be informed of communication with research participants at the next GREB meeting.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Communication – Research Participants	v.602.001 2016Mar30	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Section 700:	Informed Consent
Title:	Informed Consent Form Requirements and Documentation
SOP Code:	701.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the requirements for the Consent Form and the process for waiving or obtaining and documenting initial and ongoing informed consent.

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.

Researchers are responsible for providing GREB with a detailed description of the rationale for consent documents (or waiving consent), a description of the consent process, and the process for withdrawing consent. Researchers also are responsible for providing a description of the recruitment methods and materials.

When a Consent Form is used, the researchers and GREB are jointly responsible for ensuring that the Consent Form contains all of the basic elements of consent.

The GREB Chair or designee is responsible for reviewing Consent Forms or changes to Consent Forms if the changes meet the criteria for delegated review.

4.0 DEFINITIONS

The TCPS2 (2014), Chapter 3, uses the words “consent form” to describe the process of obtaining informed consent. However, for some GREB ethics applications, no signed consent is needed such as anonymous surveys where completion of the survey is considered implied consent. Therefore, components of the consent process are often broken into two parts called the Letter of Information (LOI) and the Consent Form (CF). In this SOP, the required elements are described as one process.

5.0 PROCEDURES

Researchers must provide prospective participants or authorized third parties with full disclosure of all of the information necessary for making a voluntary informed decision to participate in a research project.

Research participants should be able to voice in confidence their concerns and questions and request information regarding their participation or potential participation in research to an informed individual on GREB or in the GREB office.

5.1 Documentation of Informed Consent

- 5.1.1 GREB typically requires documentation of informed consent by the use of a written Consent Form ethically cleared by GREB and signed and dated by the research participant (or the research participant's legally acceptable representative);
- 5.1.2 A copy of signed Consent Forms shall be provided to research participants;
- 5.1.3 GREB may ethically clear a process that allows the Consent Form to be delivered by regular mail, email, internet, or facsimile to the potential participant, and to conduct a consent interview by telephone when the participant can read the Consent Form as it is discussed. All other applicable conditions for documentation of informed consent must be met when using this procedure;
- 5.1.4 Where consent is not documented in a signed Consent Form, researchers may use a range of consent procedures (e.g., oral consent, field notes, implied consent through the return of a completed questionnaire). The alternate procedures used to seek consent must be documented by the researchers and ethically cleared by GREB;
- 5.1.5 Whenever possible, research participants should have written documentation of participation in a research project unless it may compromise their safety or confidentiality;
- 5.1.6 Consent must be maintained throughout the research project;
- 5.1.7 All participants must be provided with information relevant to their ongoing consent to participate in the research.

5.2 GREB Review of Required Elements of Informed Consent

- 5.2.1 GREB members will review the proposed consent process for appropriateness;

5.2.2 GREB members will review the proposed consent forms for:

- general readability,
- appropriateness of the language and content,
- voluntariness of consent,
- withdrawal procedures,
- adequate information to safeguard the privacy and confidentiality of research participants and prospective participants, and
- any inadmissible language that causes the participant or the legally acceptable representative to waive or appear to waive any legal rights, or that releases or appears to release the investigator, the institution, or the sponsors from liability or negligence (see also Informed Consent Required Elements for all GREB Research [Appendix 1] for applicable consent form required elements);

5.2.3 GREB may require a separate consent form for optional procedures or sub-studies (e.g., completing a multi-stage study);

5.2.4 Following the review, GREB may approve the consent forms as submitted or require changes;

5.2.5 When changes are required by GREB and are made by the researchers, the GREB Chair or designee will review the consent forms to confirm that the required changes have been made and that the version date has been updated;

5.2.6 When the changes meet the criteria of GREB for either delegated or full board review, researchers will be asked to remove all previous versions in the Human Ethics Application System;

5.2.7 Once the ethics application and its attachments receive the final ethics clearance letter from the GREB Chair, the application will be locked from further changes by the Ethics Coordinator in the Human Ethics Application System;

- 5.2.8 If researchers wish to make changes to the Consent Form, these changes must be done through a GREB amendment form with justification provided.

5.3 Recruitment Materials

- 5.3.1 **Advertising:** GREB must first review and approve the text and the use of any advertisements, notices, media, and internet messages according to GREB requirements;
- 5.3.2 GREB reviews the recruitment materials (e.g., advertisements, letters, notices) for evidence of coercion or undue influence and consistency with the GREB ethically-cleared research, the Consent Form, and the TCPS2 (2014);
- 5.3.3 All recruitment materials that have been ethically cleared by GREB must also be approved for use by each organization where the recruitment material will be displayed.

5.4 Translation of Informed Consent Documents

- 5.4.1 The informed consent document should be in language understandable to the research participants (or acceptable representatives);
- 5.4.2 When a research participant is non-English speaking, documentation of informed consent can be by one of two methods:
- **Written consent:** GREB ethically cleared English version of the Consent Form is translated into the research participant's native language. GREB may require that translated Consent Forms be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the GREB ethically-cleared English Consent Forms. A translated Consent Form does

not replace the need for an interpreter to be present during the consent process and throughout the research. The research participant and the interpreter will sign and date the translated version of the informed consent form document,

- **Oral consent:** If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language may orally interpret the GREB ethically-cleared English Consent Form to the research participant. The oral consent process is interactive in that participants are asked if they understand and give consent to smaller segments of required statements as well as overall consent after the complete Consent Form has been read. If an audio recorder is used, the final verbal consent should be recorded before the study is conducted. If no audio recorder is used, the researcher and interpreter should record the name (or pseudonym/code number) and date of each participant's consent in a notebook. If a research participant is unable to read, the researcher should follow the oral consent process. An interpreter should be impartial and available to the research participant throughout the research.

5.5 Consent Update for Ongoing and Completed Research Participants

- 5.5.1 Researchers must inform ongoing and completed participants of any new information that might affect their willingness to participate in the research or may alter the risks of harm. If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the research participants sign a GREB ethically-cleared Consent Form containing the updated information;

- 5.5.1 If applicable, ongoing consent may be obtained orally by contacting the research participants by phone, providing the updated information, and documenting their agreement to continue;
- 5.5.2 The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the GREB.

5.6 Consent Monitoring

- 5.6.1 In considering the adequacy of informed consent procedures, GREB may require monitoring of the consent process by an impartial observer;
- 5.6.2 Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information provided;
- 5.6.3 Monitoring may also be appropriate as a corrective action when GREB has identified problems associated with particular researchers or research projects.

6 REFERENCES

[TCPS2 \(2014\), Chapter 3, Article 3.2](#)

7 APPENDICES

1. Informed Consent Required Elements for all GREB Research (TCPS2)

8 REVISION HISTORY

SOP Title	Version	Updates
Informed Consent Form Requirements and Documentation	v.701.001 2016MAR30	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 700:	Informed Consent
Title:	Waiver or Alteration of Informed Consent
SOP Code:	702.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the process for waiving or altering informed consent.

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.

Researchers are responsible for providing GREB with a detailed description of the rationale for waiving or altering informed consent.

GREB is responsible for determining whether or not informed consent exemptions or alterations are applicable and appropriate (see [TCPS2 \(2014\), Article 3.7A](#)).

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

There are instances where the normal consent procedures for research need to be waived or altered.

5.1 Waiver or Alteration of Informed Consent

5.1.1 GREB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided that GREB finds and documents that:

- The regulatory and TCPS2 (2014) ethics guidance framework supports the waiving of consent,
- The research involves no more than minimal risk to the participants,
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,

- The research could not practicably be carried out without the waiver or alteration,
- The precise nature and extent of the alteration is defined,
- The information is used in a matter that will ensure its confidentiality,
- Whenever appropriate, the participants are provided with additional pertinent information after participation (see [TCPS2 \(2014\), Article 3.7B, Debriefing in the Context of Alterations to Consent Requirements](#)),
- The research project is not prohibited by law;

5.1.2 These findings and their justifications should be clearly documented in the Human Ethics Application System as part of the delegated reviewers' comments or in the GREB Meeting minutes.

6.0 REFERENCES

[TCPS2 \(2014\), Article 3.7A](#), and [3.7B](#)

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Waiver or Alteration of Informed Consent	v.702.001 2016MAR30	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 700:	Informed Consent
Title:	Consent for Research Involving Individuals who Lack Capacity
SOP Code:	703.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the process for obtaining informed consent from individuals lacking capacity.

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.

Researchers are responsible for providing GREB with a detailed description of the participants who lack capacity to give consent from themselves.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Certain individuals may lack capacity temporarily or permanently to give capacity for themselves to take part in research. In these instances, an authorized third party may give consent on behalf of a research participant.

5.1 Consent for Research Involving Individuals who Lack Capacity

5.1.1 For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether or not to participate, GREB must ensure that at a minimum the following conditions are met:

- Researchers involve to the greatest extent possible participants who lack the capacity to consent on their own behalf in the decision-making process,
- Researchers seek and maintain consent from authorized third parties,
- The authorized third party is not one of the researchers or any other member of the research team,

- Researchers demonstrate that the research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant, researchers shall demonstrate how the research will expose the participant to only a minimal risk and how the participant's welfare will be protected during participation in the research;
- 5.1.2 If an authorized third party has consented on behalf of a person who lacks legal capacity but that person has some ability to understand the significance of the research, researchers ascertain the wishes of the person who lacks capacity with respect to participation;
- 5.1.3 Assent from participants is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent must be respected;
- 5.1.4 Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:
 - Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing,
 - Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating, and
 - Those whose capacity remains only partially developed, such as those living with permanent cognitive impairments;
- 5.1.5 If assent for research is requested, researchers must submit to GREB the proposed procedures for obtaining consent from the authorized third parties and assent from the research participants;

- 5.1.6 When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, researchers will seek the participant's consent as a condition of continuing participation;
- 5.1.7 If individuals have signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that they lose capacity or die, an authorized third party may be guided by these directives during the consent process.

6.0 REFERENCES

[TCPS2 \(2014\), Section C, Article 3.9, 3.10, and 3.11.](#)

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Consent for Research Involving Individuals who Lack Capacity	v.703.001 2016MAR30	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 700:	Informed Consent
Title:	Consent and Secondary Use of Identifiable Data
SOP Code:	704.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the process for obtaining consent for secondary use of identifiable data.

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.

Researchers are responsible for providing GREB with a detailed description of the nature of the secondary identifiable data and their intended use.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

There may be instances where researchers feel that secondary use of identifiable secondary data is essential to the research but obtaining consent for this use of these data is impossible or impracticable.

5.1 Consent and Secondary Use of Identifiable Information

5.1.1 GREB follows the [TCPS2 \(2014\), Article 5.5A](#) in regard to the secondary use of identifiable information for research purposes without obtaining consent from research participants, if the researchers are able to satisfy the following conditions:

- Identifiable information/materials is essential to the research,
- The use of identifiable information/materials without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
- The researchers will take appropriate measure to protect the privacy of individuals and to safeguard the identifiable information/materials,

- The researchers will comply with any known preferences previously expressed by individuals about any use of their information/materials,
- It is impossible or impracticable to seek consent from individuals to whom the information relates or about whom materials were collected, and
- The researchers have obtained any other necessary permission for secondary use of information/materials for research purposes;

5.1.2 In cases where secondary use of identifiable information has been ethically cleared by GREB, no further contact with the participants for additional information is permitted without submission of a new ethics application;

5.1.3 GREB follows TCPS2 (2014), Article 5.5B in regard to research that relies exclusively on the secondary use of non-identifiable information. Researchers are required to obtain GREB Ethical Clearance, but are not required to seek participant consent. For, the use of these data.

6.0 REFERENCES

[TCPS2 \(2012\), Article 5.5A and 5.5B.](#)

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Consent and Secondary Use of Identifiable Data	v.704.001 2016MAR30	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).

Section 800:	Responsibilities of Researchers
Title:	Researcher Qualifications and Responsibilities
SOP Code:	801.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the qualifications and responsibilities of researchers who engage in research involving human participants.

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. GREB must have assurance that the qualifications of new researchers are appropriate for the conduct of research.

Researchers are required to conduct research in compliance with applicable regulations and guidelines, and to comply with all Queen's University, GREB, and other applicable policies (see [SOP 105B, Conflict of Interest: Researchers' Appendices](#)).

5.1 Researcher Qualifications

- 5.1.1 Researchers must have completed appropriate training regarding the requirements of conducting and overseeing research;
- 5.1.2 For graduate students and staff members, [CORE \(Course On Research Ethics\)](#) training is required training; they must submit proof of successfully completing that training
- 5.1.3 Any concerns raised in the GREB review of researchers' qualifications will be communicated to the researchers and must be satisfied prior to GREB Ethical Clearance of the application.

5.2 Researcher Responsibilities

5.2.1 Researchers are responsible for complying with the decisions and responsibilities set out by GREB. In addition, it is researchers' responsibility to comply with all applicable policies (see Appendices) and regulations to ensure that (if applicable) they:

- are appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for protection of human research participants,
- ensure their staff members are appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for protection of human research participants,
- consider the type of research during research design and all ethical issues associated with it,
- have adequate resources to properly conduct the research and conduct the research following written SOPs,
- declare all real, potential, or perceived conflicts of interest to GREB at the time of the initial application, and as such conflicts arise,
- obtain GREB Ethical Clearance before engaging in research involving human participants,
- sign all necessary documentation, as applicable,
- safeguard all information entrusted to them and not misuse or wrongfully disclose it, as well as maintain all promises of confidentiality,
- obtain, when required, informed consent from participants in accordance with applicable regulations prior to participants' enrollment into the research, using the most current Consent Form ethically cleared by the GREB (as applicable),

- provide full disclosure to prospective participants and/or applicable third parties, of all necessary information for making an informed decision to participate in the research project,
- are inclusive in selecting participants such that participants should not be excluded on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender (including reproductive capacity), age (including children and elderly), limited capacity to consent, and other similar attributes in the context of research, unless there is a valid reason for the exclusion,
- personally conduct or supervise the described investigation(s),
- maintain a list of appropriately qualified persons to whom they have delegated significant study-related duties,
- comply with the ethically-cleared research and applicable reporting criteria to GREB, including deviations, adverse events and privacy breaches,
- do not initiate any changes in the ethically-cleared research are not initiated without GREB Review and Ethical Clearance, except where necessary to eliminate an immediate hazard to the participants,
- report premature termination or suspension of the research to GREB,
- maintain accurate and complete records according to applicable regulatory requirements,
- submit written summaries of the research status to GREB at least annually, or more frequently if required by GREB,

- submit an application for renewal of ethics clearance to GREB prior to the expiration of GREB Ethical Clearance;
- report to GREB any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research,
- notify GREB if there is a change in researchers
- notify immediately if their medical or hospital privileges are suspended, restricted, or revoked (if applicable) or should their qualifications otherwise no longer be appropriate,
- notify GREB when the research is complete;

5.2.2 Queen's University is responsible for immediately advising GREB should it become aware of any information that would indicate that the qualifications of researchers may no longer be appropriate;

5.2.3 Researchers should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. See [SOP 105B Conflict of Interest: Researcher Appendices](#)

8.0 REVISION HISTORY

SOP Title	Version	Updates
Researcher Qualifications and Responsibilities	v.801.001 2016MAR30	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Section 900:	Quality Management
Title:	External Audits or Inspections
SOP Code:	901.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the procedures to be followed before, during, and following an external inspection or audit.

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, GREB office personnel, and researchers are responsible for ensuring that the requirements of this SOP are met

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4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The U.S. Department of Health and Human Services (HHS), Office for Human Research Protection (OHRP), has the authority to audit Canadian REBs that oversee studies that are supported by the US federal government.

Sponsors, funding entities, or others authorized by regulations or agreements with the organizations may have the authority to audit or inspect research-related documents and procedures.

These audits or inspections may involve GREB; therefore, GREB must have policies in place for dealing with external audits or inspections. Researchers are responsible for notifying GREB of any planned audits or inspections of research projects overseen by GREB.

5.1 Preparing for an Inspection or Audit

- 5.1.1 The Ethics Compliance Advisor or designee will confirm with the Sponsor and/or the researchers (or inspector/auditor, as applicable) regarding the agreed dates and times of the inspection/audit, and verify the purpose of the inspection/audit, the applicable project(s) undergoing inspection/audit, and the inspection/audit plan and procedures;

- 5.1.2 The Ethics Compliance Advisor or designee will notify GREB members and GREB office personnel of the inspection/audit;
- 5.1.3 The Ethics Compliance Advisor or designee will review the inspection/audit procedures with GREB members and GREB office personnel and conduct a thorough review of the required documentation;
- 5.1.4 The Ethics Compliance Advisor or designee will arrange for access to the appropriate documents for the inspector/auditor;
- 5.1.5 The Ethics Compliance Advisor or designee will confirm that GREB members and GREB office personnel are available for interviews or to assist the inspector/auditor;
- 5.1.6 The Ethics Compliance Advisor or designee will arrange for a suitable work area (e.g., private and with sufficient space, with access to a computer and in close proximity to a photocopier and telephone) for the inspector/auditor.

5.2 Participating in an Inspection or Audit

- 5.2.1 The Ethics Compliance Advisor or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the research-specific GREB documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit;
- 5.2.2 The Ethics Compliance Advisor or designee will record the name, contact information, and title of the inspector/auditor and retain any written notices of inspection/audit for the GREB files;
- 5.2.3 The Ethics Compliance Advisor or designee will provide a brief orientation to the inspector/auditor of GREB procedures;
- 5.2.4 The Ethics Compliance Advisor or designee will provide access to the research-specific documents requested by the inspector/auditor and maintain a list of the documents reviewed;

- 5.2.5 The Ethics Compliance Advisor or designee will accompany the inspector/auditor at all times while in confidential areas of the GREB office and/or Queen's University;
- 5.2.6 The Ethics Compliance Advisor or designee will ensure that the inspector/auditor's questions are answered by the most appropriate personnel. The GREB Chair or designee, GREB office personnel, and GREB members must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;
- 5.2.7 The Ethics Compliance Advisor or designee will request meetings with the inspector/auditor at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, the GREB Chair or designee will research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available;
- 5.2.8 The Ethics Compliance Advisor or designee will ensure that the required personnel are present at the exit interview and that observations are understood before the inspector/auditors leave the facility;
- 5.2.9 The Ethics Compliance Advisor or designee will record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

5.3 Follow-up after an Inspection or Audit

- 5.3.1 The Ethics Compliance Advisor or designee will request a copy of the report from researchers if applicable;
- 5.3.2 The Ethics Compliance Advisor or designee and any other designated individuals will review any findings relevant to the GREB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken. The

response to the inspector/auditor should be coordinated through the appropriate channels (e.g., the sponsor via the researchers);

5.3.3 The Ethics Compliance Advisor or designee and any other designated individuals will institute any correction actions as applicable and revise the GREB SOPs as needed;

5.3.4 The Ethics Compliance Advisor or designee will file the original inspection/audit and response documents in the Office of Research Ethics.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
External Audits or Inspections	v.901.001 2016MAR30	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Section 900:	Quality Management
Title:	Quality Assurance Inspections
SOP Code:	902.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes processes for monitoring, evaluating, and improving the effectiveness of the human participant research protection and review process.

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.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Quality Assurance (QA), and Quality Control (QC) activities and Quality Management programs, such as inspections of GREB and of researchers, allow for a continuous evaluation and subsequent assurance of the human participant research protection and review process.

Findings from these activities and programs are measured against established policies and procedures and all applicable ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

5.1 GREB Quality Assurance Inspections (Internal)

5.1.1 The Ethics Compliance Advisor will develop a schedule for routine QA Inspections or initiate inspections in response to complaints or other concerns;

5.1.2 QA Inspections may include GREB and the GREB office;

5.1.3 When the Ethics Compliance Advisor conducts a QA Inspection of GREB and the GREB office, the inspection may including the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,

- A review of research files, GREB membership rosters, GREB attendance records, and GREB Meeting agendas and minutes,
- A review of workload, performance metrics, and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with GREB members, GREB office personnel, researchers, sponsors, and regulators,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether or not any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any feedback from sponsors, funders, research participants, and regulators relevant to the protection of the rights, safety, and well-being of research participants,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from Queen's University's policies, and whether or not the deviations require remediation,
- An assessment of compliance with all applicable requirements;

5.1.4 The Ethics Compliance Advisor compares the findings against established policies, SOPs, and applicable ethical, legal, and regulatory requirements;

- 5.1.5 The Ethics Compliance Advisor prepares a written summary of the inspection, including areas requiring improvement;
- 5.1.6 The Ethics Compliance Advisor reports the findings to the GREB Chair or designee, GREB members, and appropriate Queen's University officials, as required;
- 5.1.7 The Ethics Compliance Advisor works with the GREB Chair or designee to implement improvements (e.g., new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

5.2 Researcher Quality Assurance Inspections

- 5.2.1 The Ethics Compliance Advisor will develop a schedule for routine QA Inspections and implement inspections in response to researcher requests;
- 5.2.2 The Ethics Compliance Advisor will work with GREB and the appropriate Queen's University officials where the research is being conducted to determine if and when an inspection of a researcher's research is warranted;
- 5.2.3 GREB may direct the Ethics Compliance Advisor to conduct inspections;
- 5.2.4 The Ethics Compliance Advisor or designee may request copies of the sponsor's monitoring reports for a designated research project or the completion of a questionnaire from GREB;
- 5.2.5 The criteria for selecting researchers or research projects for inspection may include:
 - The results of a previous external audit or inspection,
 - The results of a sponsor audit,
 - Researcher-initiated studies (i.e., where the researcher is also the sponsor),
 - Studies that involve a potentially high risk to participants,

- Studies that involve vulnerable populations,
- Studies in which researchers are enrolling large numbers of participants,
- Suspected non-compliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported non-compliance,
- Participant complaints,
- Research staff complaints,
- Any other situation that GREB deems appropriate;

5.2.6 The Ethics Compliance Advisor or designee will notify the researchers of the inspection and a mutually acceptable time will be scheduled. It may be necessary to schedule an inspection without first obtaining the formal consent of researchers (e.g., participant safety or suspected non-compliance);

5.2.7 The Ethics Compliance Advisor or designee will conduct the inspection using appropriate evaluation tools;

5.2.8 When the Ethics Compliance Advisor conducts an inspection of researchers, the inspection may include some or all of the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of all regulatory binders including the GREB Ethical Clearance documentation, all versions of GREB ethically-cleared Consent Forms, signed Consent Forms, research protocols and amendment documentation, documentation for renewal of ethics clearance, correspondence between the researchers and sponsor (if applicable), etc.,
- Interviews with the research staff and/or researchers,

- A review of computer hardware and/or software associated with the research, and
 - A review of other documentation, as relevant and available;
- 5.2.9 GREB or the Ethics Compliance Advisor may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;
- 5.2.10 At the conclusion of the evaluation, the Ethics Compliance Advisor or designee will discuss the findings with the researchers;
- 5.2.11 The Ethics Compliance Advisor or designee will draft a report or provide a summary of the inspection including: positive findings, areas for improvement, and recommendations for corrective action, for submission to the GREB Chair or designee for review;
- 5.2.12 Researchers will be given an opportunity to respond to the report with clarifications and/or corrective action plans within a time specified by GREB;
- 5.2.13 The Ethics Compliance Advisor or designee will send a copy of the final report to the researchers and GREB. When applicable, the GREB Chair or designee will provide the findings to the appropriate Queen's University officials.

5.3 Corrective Action

- 5.3.1 The Ethics Compliance Advisor may recommend corrective action based on the findings;
- 5.3.2 Corrective action may include a recommendation for the provision of additional resources, training, or education, the development of or revisions to the SOPs, and changes to forms, checklists, or templates;
- 5.3.3 The Ethics Compliance Advisor will evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

5.3.4 The Ethics Compliance Advisor will follow-up with researchers in a timely manner to determine if the recommended corrective actions have been implemented.

5.4 Documentation

5.4.1 The Ethics Compliance Advisor or designee files all reports and correspondence concerning QA Inspections in the appropriate QA Files.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Quality Assurance Inspections	v.902.001 2016MAR30	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

Section 900:	Quality Management
Title:	Non-Compliance
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Site Approvals

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1.0 PURPOSE

This SOP describes the GREB process for responding to reports of non-compliance and the actions that GREB may take as a result of its review of reports of serious and/or continuing non-compliance.

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.

Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of ethical clearance of GREB.

GREB office personnel and GREB members are responsible for acting on information or reports of non-compliance received from any source. The GREB Chair or designee is responsible for the initial review of allegations of non-compliance.

If intentional, serious, or continuing non-compliance is established, GREB is responsible for determining the relevant corrective actions. GREB is also responsible for reporting any incidents of serious or continuing non-compliance to researchers and to the appropriate Queen's University officials, and has the authority to notify the regulatory authorities (as applicable), and the sponsor. GREB may delegate regulatory authority reporting to Queen's University officials if applicable.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Reports of non-compliance may come from any source including GREB members, researchers, research participants, organizational personnel, the media, or the public. The rights and welfare of research participants could be at risk if there are serious or repeated non-compliance on the part of researchers or research team members. It is, therefore, the duty of GREB to be receptive to these reports and to act on all credible allegations of non-compliance.

5.1 Reports of Non-Compliance

- 5.1.1 Reports of non-compliance in human participant research may come from many sources including, but not limited to, researchers (as a self-report), sponsor representatives, quality assurance or compliance officers, research participants, members of the research team, or persons not directly involved with the research;
- 5.1.2 Persons raising such concerns are encouraged to express them in writing. However, the GREB office will receive and document oral reports of non-compliance;
- 5.1.3 Evidence of serious or repeated non-compliance may also arise from human protection-related Quality Assurance Inspections, sponsor audits or inspections, or regulatory agency audits or inspections.

5.2 Evaluating Allegations of Non-compliance

- 5.2.1 When an allegation of non-compliance is referred to GREB, GREB office personnel document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the GREB Chair or designee and the Ethics Compliance Advisor;
- 5.2.2 The GREB Chair or designee and/or the Ethics Compliance Advisor manage all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;
- 5.2.3 The GREB Chair or designee and/or the Ethics Compliance Advisor conduct an initial review of all allegations to determine the veracity of the allegations;

- 5.2.4 The GREB Chair or designee and/or the Ethics Compliance Advisor obtain as much information as possible from the individual reporting the incident;
- 5.2.5 The GREB Chair or designee and/or Ethics Compliance Advisor obtain as much additional information as possible, or verification from other sources, by one or more of the following means:
- Contacting the researchers or research team members team directly,
 - Consulting with other relevant organizational personnel,
 - Collecting relevant documentation,
 - Reviewing any written materials,
 - Interviewing knowledgeable sources;
- 5.2.6 If the GREB Chair or designee and/or Ethics Compliance Advisor determines that there is evidence of non-compliance, he/she/ze then assesses whether the non-compliance was intentional, serious, and/or repeated;
- 5.2.7 If the GREB Chair or designee and/or Ethics Compliance Advisor determines that there is insufficient evidence to support the allegations, no further action is required.

5.3 Managing Non-Compliance

- 5.3.1 GREB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;
- 5.3.2 If the GREB Chair or designee and/or the Ethics Compliance Advisor determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance

and took appropriate corrective actions, no further action may be required;

- 5.3.3 If the GREB Chair or designee and/or the Ethics Compliance Advisor determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the GREB Chair or designee and/or the Ethics Compliance Advisor may discuss the matter directly with the researchers, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to GREB at a GREB meeting;
- 5.3.4 If it appears that researchers were intentionally non-compliant, the GREB Chair or designee and/or the Ethics Compliance Advisor may suspend the conduct of the research immediately and refer the matter to the next GREB meeting and the Director of Research Ethics Compliance. Queen's University officials will be notified as applicable;
- 5.3.5 GREB will review the information at the next GREB meeting and determine the appropriate corrective actions;
- 5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, GREB may consider one or more of the following actions:
- Request modification of the protocol,
 - Request modification of the Consent Form,
 - Require that additional information be provided to past participants,
 - Require that current participants be notified,
 - Require that current participants re-consent to participation,
 - Modify the renewal schedule,
 - Require on-site observation of the consent process,

- Suspend new enrollment of participants,
- Suspend GREB Ethical Clearance of the research,
- Suspend researcher involvement in the research,
- Terminate GREB Ethical Clearance of the research,
- Require researchers and/or staff to complete a training program,
- Notify organizational entities (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Any other action deemed appropriate by GREB.

5.4 GREB Response to Reports of Non-Compliance

- 5.4.1 The GREB Chair or designee and/or the Ethics Compliance Advisor will notify the Researcher in writing of the results of the GREB review of incidents of non-compliance and any remedial actions required;
- 5.4.2 The GREB Chair or designee and/or the Ethics Compliance Advisor will report any serious or continuing non-compliance to the researchers as well as to the Director of Research Ethics Compliance and, if applicable, Queen's University officials. GREB has the authority to report to the regulatory authorities (as applicable) and the sponsor. GREB may delegate regulatory authority reporting to Queen's University officials;
- 5.4.3 GREB may submit an allegation of research misconduct to Queen's University officials, as appropriate. Cases of scientific misconduct, which is defined as willful and intentional actions that would violate the standard codes of scholarly conduct and ethical behaviour in professional scientific research, would be considered serious.

Scientific misconduct may be related to issues such as the treatment of human participants, the honesty and integrity of experiments and research (fabrication, falsification, plagiarism, or omission of data), permissions for access to research data, undue pressure or coercion to participate in research, and policies with respect to publication and acknowledgements. More details about scientific misconduct are referenced in the [Queen's University Senate Policy on Integrity in Research](#) (Appendix 1);

- 5.4.4 Researchers will cooperate with the [Queen's University Senate Policy on Integrity in Research](#) (Appendix 1);
- 5.4.5 GREB will request a time-sensitive response in writing from the researchers, including the corrective action plan;
- 5.4.6 The researchers' response may be reviewed using a delegated GREB review procedure or the review may be referred to the GREB full board for a decision;
- 5.4.7 The GREB Chair or designee and/or Ethics Compliance Advisor will follow up to assess any corrective measures that have been implemented by the researchers.

5.5 Documenting Non-Compliance

- 5.5.1 The GREB Chair or designee and/or Ethics Compliance Advisor documents the findings of reports of non-compliance. The documentation of findings includes the allegations, the information obtained during the initial assessment, whether or not allegations of non-compliance were verified, GREB's decision and actions taken, and the researchers' response;
- 5.5.2 For those incidents of non-compliance referred to the full board, the Ethics Coordinator or designee documents the following in the GREB Meeting minutes: a description of the incident and findings,

verification of the non-compliance, GREB's decision, the remedial action required by GREB, the researchers' response and actions implemented, and plans for further follow-up.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Queen's University Senate Policy on Integrity in Research (Appendix 1)
http://www.queensu.ca/secretariat/sites/webpublish.queensu.ca.us/cwww/files/files/policies/senateandtrustees/research_integrity.pdf

8.0 REVISION HISTORY

SOP Title	Version	Updates
Non-Compliance	v.903.001 2016MAR30	Original: Adoption of standardized SOPs developed by CAHSREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAHSREB/N2 SOPs to reflect institutional policies.

GENERAL RESEARCH ETHICS BOARD (GREB)

STANDARD OPERATING PROCEDURES GLOSSARY OF TERMS

Ad Hoc Advisor	A person with relevant and competent knowledge and expertise consulted by an Research Ethics Board (REB) for a specific research ethics review, and for the duration of that review, in the event that the REB members lack specific expertise or knowledge to review with competence the ethical acceptability of a research proposal. The ad hoc advisor is not a member of the REB and is not counted in the quorum or allowed to vote on REB decisions.
Adverse Event (AE)	This term typically refers to any event that adversely affects the welfare of a participant(s) and/or researcher(s) that was not anticipated in the description of risks and procedures in the original ethics application. A serious adverse event (SAE) is an unanticipated event that has had a significant impact upon a participant(s) and/or researcher(s) in terms of physical, psychological, and/or emotional discomfort or distress.
Affiliation	A person would be considered affiliated if they were providing services for (including in an advisory capacity), receiving compensation from, or directly involved with the organization (e.g. employed by, under contract with, or in a governance role, whether paid or un-paid).
Alternate Member	A formally appointed voting member of the Research Ethics Board (REB) who may substitute for a regular member of the REB but who is not expected to attend every REB meeting. An alternate REB member's presence at the REB meeting in the place of an absent regular REB member is used to establish quorum.
Amendment	A written description of a modification or change(s) to the previously approved research study. Amendments include any changes to the protocol or related research documents, such as changes to the consent form, revisions to the Investigator Brochure, updated participant material, etc.
Assent	Affirmative agreement to participate in research by an individual unable to provide consent.
Authorized third party	Any person with the necessary authority to make decisions on behalf of the prospective participant who lacks the capacity to consent to participate, or to continue to participate, in a particular research project. (Also known as a "legally acceptable representative" or "substitute decision-maker").
CAREB	Canadian Association of Research Ethics Boards
CFR	Code of Federal regulations
CIHR	Canadian Institute of Health Research
Confidentiality	Refers to the agreement between the Researcher and the participant as to how personal data will be managed and used, and an ethical and/or

	<p>legal responsibility to safeguard information from unauthorized use, disclosure, modification, loss or theft. The term also refers to the GREB's ethical and/or legal responsibility to safeguard information in its custody from unauthorized use, disclosure, modification, loss or theft.</p>
Conflict of Interest (COI)	<p>Circumstance of a person (e.g., Researcher or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.</p> <p>Example: COI may occur when an individual's judgments and actions or an organization's actions in relation to research are, or could be, affected by personal, organizational or other interests, including, but not limited to, business, commercial or financial interests, whether of individuals, their family members, their friends, or their former, current or prospective professional associations or of the organization itself.</p> <p>Examples of secondary interests for a Researcher include the following:</p> <ul style="list-style-type: none"> • Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study; • Acts as an officer, director, or agent of the sponsor; • His/her job status or compensation is impacted by the research (e.g., payment for speaking or leading study groups on behalf of the sponsor); • Is receiving a finder's fee for the recruitment of research participants; • Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product; • Has (or family, spouse, close relationships) any equity interest in the sponsor; • Receives payments of other sorts, which are made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria); • Is intending to recruit his/her own patients as research participants; • Has identified him or herself for any other reason as having a conflicting interest (i.e., organizational conflict that may impact the research). <p>Examples of secondary interests for an REB member include the following:</p> <ul style="list-style-type: none"> • Is a Researcher or sub-Researcher on the protocol; • Is directly involved in the conduct of the research; • His/her job status or compensation is impacted by the research (e.g. research coordinator, payment for speaking/leading study groups on behalf of the sponsor);

	<ul style="list-style-type: none"> • Is receiving or expecting to receive compensation from the sponsor in which the value of the compensation could be affected by the outcome of the study; • Acts as an officer, director, or agent of the sponsor; • Has a proprietary interest (e.g., patent, trademark, copyright interest, licensing agreement) in the tested product; • Has any equity interest in the sponsor that when aggregated for the member and the member's spouse and dependent children; • Any equity interest in the sponsor (i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices); • Significant payments of other sorts, which are payments made by the sponsor exclusive of the costs of conducting the clinical research (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria); • Is in direct competition with the Researcher of the research project for limited resources, funding, sponsorship, or research participants; acts as a consultant for the sponsor; is considered a personal or professional adversary of the Researcher; • Has identified him or herself for any other reason as having a conflicting interest.
Continuing review	Any review of ongoing research conducted by a Research Ethics Board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.
Controlled Forms	Documents that require formal change control, and that form part of the permanent record of Research Ethics Board (REB) operations and processes.
CORE	Course on Research Ethics
CV	Curriculum Vitae
Data and Safety Monitoring Board (DSMB)	A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data, assessing the safety and efficacy of research procedures, and monitoring the overall conduct of the research.
Delegated review	The level of Research Ethics Board (REB) review assigned to minimal risk research studies, to minor changes in approved research and to continuing review applications that meet the delegated review criteria. Delegated reviewers are selected from among the REB membership to conduct the review.
Designee	May refer to a member of the Research Ethics Board (REB) or to the REB Office Personnel depending on the context of the statement and the accompanying requirements of the organization.
Expiry Date	The first day that the Research Ethics Board (REB) approval of the research is no longer valid without further review and approval by the REB. When the REB determines that review more than annually

	is required, the expiration date will be determined by the REB (e.g., six months from the date of the approval).
FDA	US Food and Drug Administration
Full Board Review	The level of Research Ethics Board (REB) review assigned to above minimal risk research studies. Conducted by the full membership of the REB, it is the default requirement for the ethics review of research involving human participants.
GCP	Good Clinical Practice
GREB	General Research Ethics Board. The REB at Queen's University that is responsible for reviewing Social Sciences and Humanities research
HDH	Hotel Dieu Hospital
HIC	Health Information Custodian
HSREB	Health Sciences and Affiliated Teaching Hospitals Research Ethics Board. The REB at Queen's University that is responsible for reviewing Health Sciences research.
Human genetic research	The study of genetic factors responsible for human traits and the interaction of those factors with each other, and with the environment.
IB	Investigator Brochure
ICH	International Conference on Harmonization
Impartial	Without prejudice or bias, fair; a principle of justice holding that decisions should be based on objective criteria, rather than on the basis of bias, prejudice, or preferring the benefit to one person over another.
Impracticable	Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.
Incentive	Anything offered to research participants, monetary or otherwise, to encourage participation in research.
Incidental findings	Unanticipated discoveries made in the course of research that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health- related, psychological or social. If, in the course of research, material incidental findings are discovered, Researchers have an obligation to inform the participant.
Inspection	A systematic examination and evaluation of study-related activities and documents in comparison to specified requirements and standards.
Investigational product	Refers to new or new uses of drugs, biologics, medical devices or natural health products.
JLC	Joint Liaison Committee
KGH	Kingston General Hospital
Local adverse event	Those adverse events experienced by research participants enrolled by the Researcher at the centre(s) under the jurisdiction of the Health Sciences Research Ethics Board (HSREB).
LOI	Letter of Information
Mature minor	Any individual who demonstrates adequate understanding and decision- making capacity.

Medical device trials	Clinical trials that test the safety and/or efficacy of one or more instruments used in the prevention, diagnosis, mitigation, or treatment of a disease or abnormal physical condition or the restoration, correction or modification of body function or structure.
Minimal risk	Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.
Minor change	Any change that would not materially affect an assessment of the risks and benefits of the research or the integrity of the data, and does not substantially change the specific aims or design of the study.
Multi-centre	Multi-centre means that the research is reasonably expected to be conducted at more than one centre.
Natural health product (NHP) trial	A clinical trial testing the safety and/or efficacy of one or more natural health products (NHP). The term NHP is used to describe substances such as vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, and many alternative and traditional medicines.
Non-compliance	Failure to follow applicable guidelines and regulations governing human participant research; failure to follow the protocol approved by the Research Ethics Board (REB), or failure to follow stipulations imposed by the REB as a condition of approval.
Non-controlled forms	Documents that are not part of the permanent record of Research Ethics Board (REB) operations and processes. Non-controlled forms also will contain version dates.
Non-local (external) adverse event	Those adverse events experienced by research participants enrolled by Researchers at other centres/organizations outside the GREB's jurisdiction.
NSERC	National Science and Engineering Research Council
N2	Network of Networks
Ongoing research	Research that has received Research Ethics Board (REB) approval and has not yet been completed.
Organizational Official	A senior official who signs an organization's human participants' assurance, making a commitment on behalf of the organization to comply with 45 CFR Part 46, the US Code of Federal Regulations covering protection of human participants, and with Health Canada regulations.
Participant	An individual whose data or responses to interventions, stimuli, or questions by a Researcher are relevant to answering a research question; also referred to as "human participant" and in other policies/guidance as "subject" or "research subject."
Personal Health Information Protection Act (PHIPA)	The Personal Health Information Protection Act, 2004 is an Ontario law that governs the collection, use and disclosure of personal health information within the health sector. The object is to keep personal health information confidential and secure, while allowing for the effective delivery of health care. Under this legislation, persons and organizations that provide health care are collectively known as health information "custodians".

Periodic safety update or summary report	A summary report, created by the sponsor, listing all of the reported unexpected serious adverse events that have occurred in a given reporting period, and which includes any significant areas of concern and the evolving safety profile of the investigational product.
Personal Health Information (PHI)	<p>Personal health information (PHI), is a subset of Personal information which is identifiable information about an individual. (See “Identifiable information” which also is “personal information”)</p> <p>Personal health information is identifying information about an individual in either an oral or in a recorded form, if the information:</p> <ul style="list-style-type: none"> • Relates to the individual’s physical or mental health, including family health history; • Relates to the provision of health care, including the identification of persons providing care; • Is a plan of service for an individual requiring long-term care; • Relates to payment or eligibility for health care; • Relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances; • Is the individual’s health number; or • Identifies an individual’s substitute decision-maker. <p>Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.</p>
Personal Information (PI)	<p>Information that identifies an individual and/or for which it is foreseeable that may reasonably be expected to identify an individual, alone or in combination with other available information.</p> <p>Directly identifying information: the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).</p> <p>Indirectly identifying information: the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, or unique personal characteristic).</p> <p>Coded information: direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the Researcher retains a list that links the participant’s code name with their actual name so data can be re-linked if necessary).</p> <p>Anonymized information: the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.</p> <p>Anonymous information: the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.</p>

PIPEDA	Personal Information Protection and Electronic Documents Act. Federal legislation that protects personal information, including health information. PIPEDA's primary purpose is to govern the collection, use and disclosure of personal information in recognition of the realities of electronic commerce. It was not developed to specifically deal with health information
PM	Product Monograph
PRE	Panel on Research Ethics
Privacy	An individual's right to be free from intrusion or interference by others. Privacy refers to persons and their interest in controlling the access of others to themselves (their personal information).
Privacy breach	The unauthorized collection, use, or disclosure of personal information or personal health information (PHI) in the custody and control of an individual or a Health Information Custodian (HIC) or in the custody and control of the organization or its affiliated partners.
Proportionate approach to research ethics review	The assessment of foreseeable risk to determine the level of scrutiny the research will receive (i.e., delegated review for minimal risk research or full Research Ethics Board (REB) review for research above minimal risk), as well as the consideration of foreseeable risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.
Protocol deviation	The term protocol deviation is not well defined by regulations or guidelines, but deviations are identified as any unplanned or unforeseen change to a Research Ethics Board (REB) approved protocol or protocol procedures. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended at the time to modify the entire protocol.
Quorum	A simple majority of Research Ethics Board (REB) Members (50% + 1), who collectively have sufficient expertise in the scientific, methodological and clinical areas of the research under review and are knowledgeable about relevant ethical and legal matters. The quorum will include at least one community member and a member whose primary experience and expertise are in a non-scientific discipline. Quorum includes REB Members participating by telephone or video conference. Quorum also includes Alternate REB Members substituting for regular REB Members in the same membership category.
Renewal (of Ethics Clearance)	Any review of ongoing research conducted by a Research Ethics Board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.
Reportable event	Includes anything that could significantly impact the conduct of the research or alter the Research Ethics Board's (REB) approval or favourable opinion to continue the research.
Research	An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Researcher	The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. (Also known as “Qualified Investigator”).
Research Ethics Board (REB)	A body of Researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an organization to review the ethical acceptability of all research involving humans conducted within the organization’s jurisdiction or under its auspices.
Research Ethics Board (REB) of record	The Research Ethics Board (REB) that has been granted ultimate authority for the ethics review and oversight of a research study.
Risk	The possibility of the occurrence of harm. The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or to third parties.
ROMEO	Process Pathway’s Human Ethics Application System software
SAE	Serious Adverse Event
SCOC	Stem Cell Oversight Committee
SEAMO	Southeastern Ontario Academic Medical Organization
SOP	Standard Operating Procedure
SSHRC	Social Sciences and Humanities Research Council
Suspension	A temporary or permanent halt to all research activities pending future action by the Research Ethics Board (REB), by the sponsor and/or by the Researcher.
TCPS2	TCPS 2 (2014) - the latest edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada).
Termination	A permanent halt by the Research Ethics Board (REB), by the sponsor and/or by the Researcher to all or some research activities.
TRAQ	Tools for Research at Queen’s (TRAQ lets you submit internal research documents electronically (grant and contracts submission forms, research approval applications, revisions, event forms).
Unanticipated issues	Issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants’ welfare; and were not anticipated by the Researcher in the research proposal submitted for research ethics review.
Unanticipated problem	Any incident, experience, or outcome (including an adverse event) that meets all of the following criteria: <ul style="list-style-type: none"> • Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related

	<p>documents, such as the Research Ethics Board (REB) approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the research participant population being studied; and</p> <ul style="list-style-type: none"> • +Related or possibly related to participation in the research, (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the [investigational product(s)] or procedures involved in the research); and • Suggests that the research places research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized. <p>*Unexpected: an event is “unexpected” when its specificity and severity are not accurately reflected in the protocol-related documents such as the Research Ethics Board (REB) approved research protocol, the Investigator Brochure, or the current REB approved informed consent document, or other relevant sources of information such as product labelling and package inserts; or when the event is not associated with the expected natural progression of any underlying disease, disorder, predisposing risk factor, or condition of the participant(s) experiencing the adverse event.</p> <p>+Related to the research procedures: an event is “related to the research procedures” if in the opinion of the Researcher or sponsor, the event was more likely than not to be caused by the research procedures.</p>
USW	United Steel Workers