
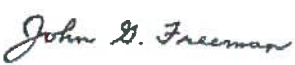



Section 100:	General Administration
Title:	Authority and Purpose
SOP Code:	101.001
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
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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).

