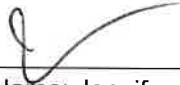




Section 100:	General Administration
Title:	Authority and Purpose
SOP Code:	101.002
Effective Date:	2019APR24

Site Approvals

Signature of Responsible Individual:		
Manager, Research Ethics Compliance		Date 2019 APR 24
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		Date 2019 APR 24
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		Date 2019 APR 24
	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 Health Sciences Research Ethics Board (HSREB) is established and empowered;
2. Define the purpose of the HSREB;
3. State the principles governing the HSREB to assure that the rights and welfare of participants are protected;
4. State the authority of the HSREB.

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

Queen's University and Affiliated Teaching Hospital Officials, all HSREB members and HSREB 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 Principal of Queen's University has invested in the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB), the authority to clear, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants and human biological materials from living and deceased individuals, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells, which is conducted within or by members of Queen's University and Affiliated Teaching Hospitals, that does not fall under the General Research Ethics Board (GREB) jurisdiction. In some circumstances discussions between the HSREB and GREB Chairs or Ethics Office Personnel are required to determine which board is best suited to review research submissions. The HSREB 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 their decisions and to ensure that decisions are made in accordance with University and Affiliate policies.

Queen's University and Affiliated Teaching Hospitals maintain an arms-length relationship with the HSREB. The HSREB is independent in its decision making and is accountable to the Principal through the Vice-Principal (Research) of Queen's University. The administration of Queen's University or Affiliated Teaching Hospitals may not override negative HSREB decisions reached on grounds of non-compliance with research ethics. Similarly, the HSREB may not override Queen's University and Affiliated Teaching Hospital decisions to not allow certain research within its jurisdiction, even if the HSREB has found it ethically acceptable.

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

5.1 Board of Record Agreement

5.1.1 In June of 1992, the HSREB was instituted as a committee of the University by the Principal, Dr. David C. Smith. The agreement of the Joint Liaison Committee (JLC), which encompasses Queen's University, Kingston General Hospital (KGH), Hotel Dieu Hospital (HDH), St. Mary's of the Lake Hospital, Kingston Frontenac Lennox & Addington Health Unit, outlined that the HSREB would review all research protocols involving human participants. In 1993, the

- School of Nursing (January) and the Kingston Psychiatric Hospital (April) were added to the agreement;
- 5.1.2 The affiliation agreement was updated in July 2017 between Queen's University and the Kingston Health Sciences Centre (KHSC), which is specific to Kingston General Hospital (KGH) and Hotel Dieu Hospital (HDH) sites;
 - 5.1.3 The affiliation agreement was updated in March 2018 between Queen's University and Providence Care Centre (PCC);
 - 5.1.4 The affiliation agreements specify that the HSREB will act as the "REB of Record" for the Affiliated Teaching Hospitals Kingston Health Sciences Centre KHSC (HDH and KGH Sites) and Providence Care Centre (PCC);
 - 5.1.5 The affiliation agreement specifies that all Hospital and University Personnel while involved in research activities at the Hospital are required to be trained in and adhere to the relevant Hospital, University and Regulatory policies concerning ethical conduct, research integrity and conflict of interest and commitment, including but not limited to the: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014), Declaration of Helsinki – Ethical Principles for Medical research Involving Human Subjects, International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use-Good Clinical Practice Guideline, University Conflict of Interest Policy, University Integrity in Research Policy and the University Research Administration Policy;
 - 5.1.6 All hospital research involving human participants or human participant data, which includes data received directly from individuals and/or their medical records, shall require prior clearance in writing from the HSREB.

5.2 Reporting and Financial Relationship

- 5.2.1 The Director, 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 the HSREB can fulfill its mandate.

5.3 Statement of Authority

- 5.3.1 Queen's University and Affiliated Teaching Hospitals have authorized the HSREB to review research involving human participants conducted under the auspices of Queen's University and the Affiliated Teaching Hospitals;
- 5.3.2 The HSREB is established and empowered under the authority of Queen's University and Affiliated Teaching Hospitals. Queen's

University and the Affiliated Teaching Hospitals require that all research involving human participants be reviewed and cleared by a REB prior to initiation of any research related activities;

- 5.3.3 The chairperson of the HSREB will be appointed by the University's Principal on the advice of the Vice-Principal (Research) after consultation with the Hospital;
- 5.3.4 Queen's University and Hospital researchers must be trained in and adhere to the relevant Hospital, University and Regulatory policies concerning ethical conduct, research integrity and conflict of interest and commitment, including but not limited to the: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014), Declaration of Helsinki – Ethical Principles for Medical research Involving Human Subjects, International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use-Good Clinical Practice Guideline, University Conflict of Interest Policy, University Integrity in Research Policy and the University Research Administration Policy.

5.4 Purpose of the HSREB

- 5.4.1 The HSREB's purpose is to protect the rights and welfare of human participants participating in research;
- 5.4.2 The HSREB 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;
- 5.4.3 These include, but are not limited to, the Food and Drugs Act, the International Conference on Harmonisation Good Clinical Practice Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014), and where applicable, US Federal Regulations.

5.5 Governing Principals

- 5.5.1 The HSREB 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, to 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:
- Obligation to treat people fairly with equal respect and concern,
 - Vulnerable or marginalized people may need to be afforded special attention.

5.6 HSREB Authority

5.6.1 The HSREB is established to review all research involving human participants within its established jurisdiction;

5.6.2 The HSREB 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 the HSREB 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, 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 the HSREB 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 the HSREB's jurisdiction.

5.7 Research Subjects to US Regulations

5.7.1 The HSREB 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.

6.0 REFERENCES

See References.

7.0 APPENDICIES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Authority and Purpose	v.101.001 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.
Authority and Purpose	v.101.002 2019APR24	<ol style="list-style-type: none"> 1. Section 5.1: Updated to reflect new affiliation agreements for Kingston Health Sciences Centre (KHSC) and Providence Care Centre (PCC). 2. Section 5.3: Updated to reflect the appointment process of the HSREB Chair and the ethics training and adherence expectation for Health Science researchers.