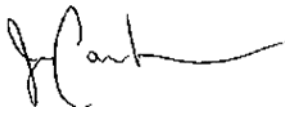




Section 100:	General Administration
Title:	HSREB Training and Education
SOP Code:	103.002
Effective Date:	2020DEC14

Site Approvals

Signature of Responsible Individual:		
Manager, Research Ethics Compliance		Date
	Name: Jennifer Couture	
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.