




Section 300:	Functions and Operations
Title:	HSREB Submission Requirements and Administrative Review
SOP Code:	301.001
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22
	Name: Jennifer Couture	Date
Approval Authority:		
Chair, HSREB		May 22, 2015
	Name: Dr. Albert Clark	Date
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015
	Name: Dr. Andrew Winterborn	Date

1.0 PURPOSE

This SOP describes the HSREB submission requirements and the 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

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 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

HSREB 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.

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

The requirements for HSREB submissions are made available to all Researchers. HSREB Office Personnel are responsible for maintaining and disseminating this information to Researchers.

5.1 Submission Requirements

- 5.1.1 The required documents, format and submission dates and procedures are outlined on the HSREB website and within the online submission program TRAQ (Tools for Research at Queen's) using the ROMEO interface. Additional resources such as templates and checklists can be found on the HSREB website, which may include, but are not limited to:
- HSREB application guidelines,
 - Submission checklist,
 - Renewal form,
 - Multi-use Amendment form,
 - Serious Adverse Event (Non-Local) Reporting form,
 - Adverse Event (Local) form,
 - Informed consent form required elements checklist;
- 5.1.2 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 recommended for all faculty researchers;
- 5.1.3 The HSREB may request any additional documentation it deems necessary for the ethics review, or for research ethics oversight;
- 5.1.4 **Research Requirements:** The research question and methodology should be written in sufficient detail, in the form of a protocol, to permit evaluation of the merit of the project. The research should

include all of the required elements applicable to the research such as, but not limited to:

- A Peer Review (if applicable),
- Research rationale and objectives,
- Design and detailed description of methodology,
- Eligibility criteria, description of the population to be studied,
- Recruitment and consent process,
- Research interventions,
- Treatment allocation (if applicable),
- Primary and secondary outcome measures,
- Assessment of safety,
- Sample size justification,
- Data analysis,
- Data monitoring;

5.1.3 Refer to SOP 403 Initial Review – Criteria for HSREB Ethics Clearance for more information regarding application requirements.

5.2 Administrative Review Procedures

- 5.2.1 The ROMEO file number is generated by the ROMEO electronic system at the time the application is initiated;
- 5.2.2 A unique 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 HSREB Ethics Coordinator or designee performs an administrative review of the submission for overall completeness;
- 5.2.4 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the HSREB Ethics Coordinator or designee will follow up with the Researcher and/or research coordinator to request the required information for inclusion with the submission;
- 5.2.5 Upon receipt of a complete submission, the responsible HSREB Ethics Coordinator or designee identifies any outstanding items that will be required to undergo ethics review, as applicable;
- 5.2.6 For submissions requiring Full Board review, the HSREB Ethics Coordinator or designee posts the submission to the agenda of the next Full Board meeting. Primary and secondary reviewers are assigned once the agenda is complete, if applicable;
- 5.2.7 For submissions reviewed via delegated review procedures, the HSREB Ethics Coordinator or designee assigns the review to the HSREB Chair or designee, who in turn may assign an additional reviewer for the research project.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 NONE. REVISION HISTORY

SOP Title	Version	Updates
HSREB Submission Requirements and Administrative Review	v.301.001 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.