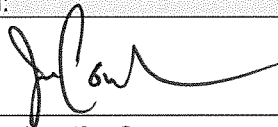
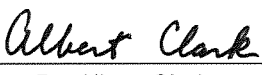
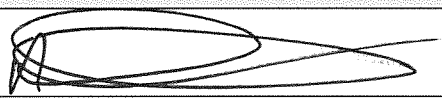


Section 600:	HSREB Communication and Notification
Title:	HSREB Research Communication
SOP Code:	602.003
Effective Date:	2016SEP12

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016 sep 14
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		Date: Sept 14, 2016
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016 sep 15
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for research participants and any other individuals (e.g., the legal guardian of a research participant, a researcher, a Queen’s University and/or affiliated teaching hospital staff or faculty member, a REB member, etc.) to communicate with the HSREB regarding any ethics concerns, for studies conducted under the authority of the Queen’s University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (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

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

Research participants and any other individuals (e.g., the legal guardian of a research participant, a researcher, a Queen's University and/or affiliated teaching hospital staff or faculty member, a REB member, etc.) should be able to voice their concerns, questions and request information regarding their participation, potential participation, or with respect to their role in the research, in confidence, to an informed individual on the HSREB or in the HSREB office.

5.1 Communication with Research Participants and Other Individuals

- 5.1.1 Research participants or any other individual(s) that may have a concern or complaint regarding a research study conducted under the authority of the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) are encouraged to contact the HSREB office, using the contact information provided in the informed consent document(s), or as outlined in the document [HSREB Research Complaint Process \(Appendix 1\)](#), or as noted on the [HSREB website](#).
- 5.1.2 HSREB Office Personnel will communicate any concerns to the HSREB Chair or designee and other applicable Office Personnel;
- 5.1.3 The HSREB Chair or designee and other applicable Office Personnel work to resolve concerns or complaints, which may include follow-up with the Researcher or the Researcher's supervisor or other Queen's University and Affiliated Teaching Hospital(s) representative(s), and with appropriate federal agencies, as applicable;
- 5.1.4 The HSREB Chair or designee and/or other applicable Office Personnel documents all communication with the research participant or other individual(s), and a record of this communication is maintained securely in the Office of Research Ethics;
- 5.1.5 If requested, the identity of the participant and/or individual(s) will not be recorded or shared;
- 5.1.6 A de-identified record of communication will be maintained securely in the research file, as applicable;
- 5.1.7 HSREB members will be informed of communication with research participants or other individual(s) at the next HSREB full board meeting, as applicable.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. HSREB Research Complaint Process

8.0 REVISION HISTORY

SOP Title	Version	Updates
Communication – Research Participants	v.602.001 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.
Communication – Research Participants	v.602.002 2016MAR31	Scope Revised. Changes made to 5.1.5 to clarify procedure. Added Appendix: Research Participant Complaint Process.
Communication – Research Participants	v.602.003 2016SEP12	<ol style="list-style-type: none">1. Scope changed back to original description.2. Title and document updated to encompass all HSREB complaints and concerns, not just research participants.3. 5.1.1: Added additional guidance for contacting the HSREB using HSREB Research Complaint Process (Appendix 1) and HSREB website.4. 5.1.4: Added reference to other Office Personnel and updated the storage location to the Office of Research Ethics.5. Appendix 1 HSREB Research Complaint Process added.6. Title and document updated to encompass all HSREB complaints and concerns, not just research participants.



APPENDIX 1

QUEEN'S UNIVERSITY HEALTH SCIENCES AND AFFILIATED TEACHING HOSPITALS RESEARCH ETHICS BOARD (HSREB)

RESEARCH COMPLAINT PROCESS

Talk to Us

If you have concerns regarding a research study conducted under the authority of Queen's University, Kingston General Hospital, Hotel Dieu Hospital, Providence Care Centre, or the Kingston Frontenac Lennox & Addington Health Unit; please contact the HSREB Ethics Office.

Our Contact information

Toll Free Telephone in North America: 1-844-535-2988

Email: HSREB Chair at clarkaf@queensu.ca

Our Role

Your welfare is our concern. If you have any ethics concerns or complaints about a research study, please contact the HSREB Ethics Office.

What We Will Do

- We will listen to you and address your concerns,
- We will respect your confidentiality,
- We will keep you informed about the progress of the review and its conclusion.

HSREB has the authority to stop a research study until action has been taken to remedy the identified problem.