
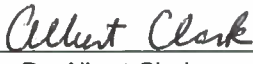



Section 600:	HSREB Communication and Notification
Title:	Communication – Researcher
SOP Code:	601.001
Effective Date:	2015MAY25

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 communication with the Researcher and with his/her research team.

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

In the interest of enhancing human research participant protection, it is important for the HSREB to foster collaboration and open communication between and among the HSREB, Researcher, research staff, and Queen's University and Affiliated Teaching Hospital representatives. This applies not only to communication related to a specific research project, but also to communication related to ethical issues and HSREB processes, policies and procedures.

All Researchers participating in HSREB cleared research shall be informed, in writing, of all determinations made by the HSREB regarding specific research. Feedback from Researchers should be encouraged and should be considered as an opportunity to review and to improve the function of the HSREB and of the HSREB office procedures.

In order to facilitate clear and accurate communication with Researchers and research staff, the HSREB will follow standardized notification and documentation procedures.

5.1 Notification of HSREB Decisions

- 5.1.1 The HSREB will notify the Researcher and/or his/her research staff of the HSREB's decision following the review (i.e., from the HSREB meeting or delegated review date) of new research, modifications, or amendments to currently ethically cleared research, applications for renewal or reportable events;
- 5.1.2 The determinations of the HSREB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);
- 5.1.3 If the research does not receive initial ethics clearance or is not cleared for renewal of ethics clearance, the HSREB Ethics Coordinator will notify the Researcher of the HSREB's decision by formal written notification;
- 5.1.4 The HSREB Chair or designee will review the draft HSREB review letter, make revisions as necessary, and will indicate his/her approval;
- 5.1.5 The HSREB review letter will be issued to the Researcher(s);
- 5.1.6 The Researcher will be asked to include the HSREB ROMEO number assigned to the research in all subsequent correspondence with the HSREB;
- 5.1.7 Upon receipt of the Researcher response to the HSREB review letter, the HSREB will follow-up with the Researcher and/or his/her staff to request any additional clarifications as needed, or as requested by the HSREB Chair or designee, or the reviewers;
- 5.1.8 Once all of the HSREB conditions are satisfied, the HSREB Ethics Coordinator or designee will issue an ethical clearance letter on behalf of the HSREB.

5.2 Research Appeal of HSREB Decision

- 5.2.1 A Researcher may request a reconsideration or appeal the decision of the HSREB and/or any of the revisions to the research requested by the HSREB;
- 5.2.2 The appeal process is outlined in SOP 402 HSREB Review Decisions and is conducted in accordance with established Queen's University and Affiliated Teaching Hospital(s) policies and procedures;
- 5.2.3 Only the HSREB may lift a restriction or re-review previous research that was not granted ethics clearance. Delegated review procedures may not be used.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Communication – Researcher	v.601.001 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.

