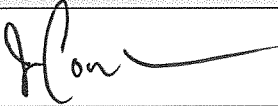




<b>Section 900:</b>	<b>Quality Management</b>
<b>Title:</b>	<b>HSREB Non-Compliance</b>
<b>SOP Code:</b>	<b>903.003</b>
<b>Effective Date:</b>	<b>2016SEP12</b>

### Site Approvals

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

## 1.0 PURPOSE

This Standard Operation Procedure (SOP) describes the HSREB process for responding to reports of non-compliance and the actions that the HSREB may take as a result of serious and/or continuing non-compliance.

## 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.

Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of ethical clearance of the HSREB.

The HSREB Office Personnel and the HSREB members are responsible for acting on information or reports of non-compliance received from any source.

The HSREB Chair or designee and/or the Ethics Compliance Advisor or designee are responsible for the initial review of allegations of non-compliance.

If intentional, serious or continuing non-compliance is established, the HSREB is responsible for determining the relevant corrective actions.

The HSREB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate Queen's University and Affiliated Teaching Hospital Official(s), and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The HSREB may delegate regulatory authority reporting to Queen's University and Affiliated Teaching Hospital Official(s) if applicable.

## **4.0 DEFINITIONS**

See Glossary of Terms.

## **5.0 PROCEDURES**

Reports of non-compliance may come from any source including the HSREB members, Researchers, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the HSREB to be receptive to these reports and to act on all credible allegations of non-compliance.

### **5.1 Reports of Non-Compliance**

- 5.1.1 The Researcher or research staff should report any incidents of non-compliance promptly to HSREB through the submission of a Protocol Deviation Report in TRAQ;
- 5.1.2 Reports of non-compliance in human participant research may come from many sources including, but not limited to, a Researcher (as a self-report), a sponsor representative, a quality assurance or compliance office, a research participant, a member of the research team, or a person not directly involved with the research;
- 5.1.3 Persons raising such concerns are encouraged to express them in writing. However, the HSREB office will receive and document oral reports of non-compliance;
- 5.1.4 Evidence of serious or repeated non-compliance may also arise from human protection-related Quality Assurance inspections,

sponsor audits or inspections, or regulatory agency audits or inspections.

## **5.2 Evaluating Allegations of Non-compliance**

- 5.2.1 When an allegation of non-compliance is referred to the HSREB, the HSREB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the HSREB Chair or designee and/or the Ethics Compliance Advisor;
- 5.2.2 The HSREB Chair or designee and/or the Ethics Compliance Advisor manage all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;
- 5.2.3 The HSREB Chair or designee and/or the Ethics Compliance Advisor will conduct an initial review of all allegations to determine the legitimacy of the allegations;
- 5.2.4 The HSREB Chair or designee and/or the Ethics Compliance Advisor will obtain as much information as possible from the individual reporting the incident;
- 5.2.5 The HSREB Chair or designee and/or Ethics Compliance Advisor will obtain as much information as possible, or verification from other sources by one or more of the following means:
  - Contacting the Researcher or member of the investigative team directly,
  - Consulting with other relevant organizational personnel,
  - Collecting relevant documentation,
  - Reviewing any written materials,
  - Interviewing knowledgeable sources;
- 5.2.6 If the HSREB Chair or designee and/or Ethics Compliance Advisor determines that there is evidence of non-compliance, he/she will then assess whether the non-compliance was intentional, serious and/or repeated;
- 5.2.7 If the HSREB Chair or designee and/or Ethics Compliance Advisor determines that there is insufficient evidence to support the allegations, no further action will be required.

## **5.3 Managing Non-Compliance**

- 5.3.1 The HSREB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;
- 5.3.2 If the HSREB Chair or designee and/or the Ethics Compliance Advisor determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance

and took appropriate corrective actions, no further action may be required;

- 5.3.3 If the HSREB Chair or designee and/or the Ethics Compliance Advisor determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the HSREB Chair or designee and/or the Ethics Compliance Advisor may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the HSREB at a Full Board meeting;
- 5.3.4 If it appears that a Researcher was intentionally non-compliant, the HSREB Chair or designee and/or the Ethics Compliance Advisor may suspend the conduct of the research immediately and refer the matter to the next HSREB Full Board meeting and/or the Director of Research Ethics Compliance. Queen's University and/or Affiliated Teaching Hospital Official(s) will be notified as applicable;
- 5.3.5 The HSREB will review the information at the next Full Board meeting and determine the appropriate corrective actions;
- 5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the HSREB may consider one or more of the following actions:
  - Request modification of the protocol,
  - Request modification of the informed consent document(s),
  - Require that additional information be provided to past participants,
  - Require that current participants be notified,
  - Require that current participants re-consent to participation,
  - Modify the renewal schedule,
  - Require on-site observation of the consent process,
  - Suspend recruitment and enrollment of new participants,
  - Suspend HSREB ethical clearance of the research,
  - Suspend Researcher involvement in the research,
  - Terminate HSREB ethical clearance of the research,
  - Require the Researcher and/or staff to complete a training program,
  - Notify organizational entities (e.g., legal counsel, risk management),
  - Ensure that all other regulatory reporting requirements are met, as required,
  - Any other action deemed appropriate by the HSREB.

## **5.4 HSREB Response to Reports of Non-Compliance**

- 5.4.1 The HSREB Chair or designee and/or the Ethics Compliance Advisor will notify the Researcher in writing of the results of the HSREB review of incidents of non-compliance and any remedial actions required;
- 5.4.2 The HSREB Chair or designee and/or the Ethics Compliance Advisor will report any serious or continuing non-compliance to the Researcher as well as to the Director of Research Ethics Compliance and if applicable Queen's University and Affiliated Teaching Hospital Official(s). The HSREB has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The HSREB may delegate regulatory authority reporting to Queen's University and Affiliated Teaching Hospital Official(s);
- 5.4.3 The HSREB may submit an allegation of research misconduct to the Queen's University and Affiliated Teaching Hospital Official(s) as appropriate; Cases of scientific misconduct, which is defined as willful and intentional actions that would violate the standard codes of scholarly conduct and ethical behavior in professional scientific research, would be considered serious. Scientific misconduct may be related to issues such as the treatment of human participants, the honesty and integrity of experiments and research (fabrication, falsification, plagiarism or omission of data), permissions for access to research data, undue pressure or coercion to participate in research and policies with respect to publication and acknowledgements. More details about scientific misconduct are referenced in the [Queen's University Senate Policy on Integrity in Research \(Appendix 1\)](#);
- 5.4.4 The Researcher shall cooperate with the [Queen's University Senate Policy on Integrity in Research \(Appendix 1\)](#);
- 5.4.5 The HSREB will request a time-sensitive response in writing from the Researcher, including the corrective action plan;
- 5.4.6 The Researcher's response may be reviewed using a delegated HSREB review procedure or the review may be referred to the HSREB, for a decision from the Full Board;
- 5.4.7 The HSREB Chair or designee and/or Ethics Compliance Advisor will follow-up to assess any corrective measures implemented by the Researcher.

## **5.5 Documenting Non-Compliance**

- 5.5.1 The HSREB Chair or designee and/or Ethics Compliance Advisor will document the findings of reports of non-compliance. The report will include the allegations, the information obtained during the

initial assessment, whether allegations of non-compliance were verified, the HSREB's decision and actions taken, and the Researcher's response;

- 5.5.2 For those incidents of non-compliance referred to the Full Board, the HSREB Ethics Coordinator or designee will document the following in the HSREB meeting minutes: a description of the incident and findings, verification of the non-compliance, the HSREB's decision, the remedial action required by the HSREB, the Researcher's response and actions implemented and plans for further follow-up.

## 6.0 REFERENCES

See References.

## 7.0 APPENDICES

1. [Queen's University Senate Policy on Integrity in Research \(Appendix 1\)](#)

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
HSREB Non-Compliance	v.903.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAHSREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAHSREB/N2 SOPs to reflect institutional policies.
HSREB Non-Compliance	v.903.002 2016JAN28	Scope revised, definition of non-compliance added, examples of non-compliance added.
HSREB Non-Compliance	v.903.003 2016SEP12	<ol style="list-style-type: none"> <li>1. Scope revised back to original,</li> <li>2. Definitions removed from SOP and added to glossary of terms.</li> <li>3. Examples of non-compliance removed (section 5.1),</li> <li>4. Procedures revised back to original form.</li> <li>5. Hyperlink to Appendix 1 added.</li> </ol>