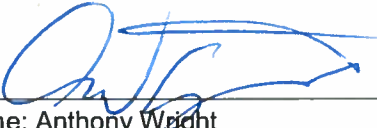




Section 900:	Quality Management
Title:	Non-Compliance
SOP Code:	903.001
Effective Date:	2016MARCH30

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the GREB process for responding to reports of non-compliance and the actions that GREB may take as a result of its review of reports of serious and/or continuing non-compliance.

2.0 SCOPE

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB's oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and administrative research conducted under the auspice of Queen's University. The scope of GREB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants."

3.0 RESPONSIBILITIES

All GREB members and GREB 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 GREB.

GREB office personnel and GREB members are responsible for acting on information or reports of non-compliance received from any source. The GREB Chair or designee is responsible for the initial review of allegations of non-compliance.

If intentional, serious, or continuing non-compliance is established, GREB is responsible for determining the relevant corrective actions. GREB is also responsible for reporting any incidents of serious or continuing non-compliance to researchers and to the appropriate Queen's University officials, and has the authority to notify the regulatory authorities (as applicable), and the sponsor. GREB may delegate regulatory authority reporting to Queen's University officials if applicable.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Reports of non-compliance may come from any source including GREB members, researchers, research participants, organizational personnel, the media, or the public. The rights and welfare of research participants could be at risk if there are serious or repeated non-compliance on the part of researchers or research team members. It is, therefore, the duty of GREB 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 Reports of non-compliance in human participant research may come from many sources including, but not limited to, researchers (as a self-report), sponsor representatives, quality assurance or compliance officers, research participants, members of the research team, or persons not directly involved with the research;
- 5.1.2 Persons raising such concerns are encouraged to express them in writing. However, the GREB office will receive and document oral reports of non-compliance;
- 5.1.3 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 GREB, GREB office personnel document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the GREB Chair or designee and the Ethics Compliance Advisor;
- 5.2.2 The GREB 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 GREB Chair or designee and/or the Ethics Compliance Advisor conduct an initial review of all allegations to determine the veracity of the allegations;

- 5.2.4 The GREB Chair or designee and/or the Ethics Compliance Advisor obtain as much information as possible from the individual reporting the incident;
- 5.2.5 The GREB Chair or designee and/or Ethics Compliance Advisor obtain as much additional information as possible, or verification from other sources, by one or more of the following means:
- Contacting the researchers or research team members team directly,
 - Consulting with other relevant organizational personnel,
 - Collecting relevant documentation,
 - Reviewing any written materials,
 - Interviewing knowledgeable sources;
- 5.2.6 If the GREB Chair or designee and/or Ethics Compliance Advisor determines that there is evidence of non-compliance, he/she/ze then assesses whether the non-compliance was intentional, serious, and/or repeated;
- 5.2.7 If the GREB Chair or designee and/or Ethics Compliance Advisor determines that there is insufficient evidence to support the allegations, no further action is required.

5.3 Managing Non-Compliance

- 5.3.1 GREB 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 GREB 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 GREB 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 GREB Chair or designee and/or the Ethics Compliance Advisor may discuss the matter directly with the researchers, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to GREB at a GREB meeting;
- 5.3.4 If it appears that researchers were intentionally non-compliant, the GREB Chair or designee and/or the Ethics Compliance Advisor may suspend the conduct of the research immediately and refer the matter to the next GREB meeting and the Director of Research Ethics Compliance. Queen's University officials will be notified as applicable;
- 5.3.5 GREB will review the information at the next GREB 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, GREB may consider one or more of the following actions:
 - Request modification of the protocol,
 - Request modification of the Consent Form,
 - 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 new enrollment of participants,
- Suspend GREB Ethical Clearance of the research,
- Suspend researcher involvement in the research,
- Terminate GREB Ethical Clearance of the research,
- Require researchers 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 GREB.

5.4 GREB Response to Reports of Non-Compliance

- 5.4.1 The GREB Chair or designee and/or the Ethics Compliance Advisor will notify the Researcher in writing of the results of the GREB review of incidents of non-compliance and any remedial actions required;
- 5.4.2 The GREB Chair or designee and/or the Ethics Compliance Advisor will report any serious or continuing non-compliance to the researchers as well as to the Director of Research Ethics Compliance and, if applicable, Queen's University officials. GREB has the authority to report to the regulatory authorities (as applicable) and the sponsor. GREB may delegate regulatory authority reporting to Queen's University officials;
- 5.4.3 GREB may submit an allegation of research misconduct to Queen's University officials, 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 behaviour 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 Researchers will cooperate with the [Queen's University Senate Policy on Integrity in Research](#) (Appendix 1);
- 5.4.5 GREB will request a time-sensitive response in writing from the researchers, including the corrective action plan;
- 5.4.6 The researchers' response may be reviewed using a delegated GREB review procedure or the review may be referred to the GREB full board for a decision;
- 5.4.7 The GREB Chair or designee and/or Ethics Compliance Advisor will follow up to assess any corrective measures that have been implemented by the researchers.

5.5 Documenting Non-Compliance

- 5.5.1 The GREB Chair or designee and/or Ethics Compliance Advisor documents the findings of reports of non-compliance. The documentation of findings includes the allegations, the information obtained during the initial assessment, whether or not allegations of non-compliance were verified, GREB's decision and actions taken, and the researchers' response;
- 5.5.2 For those incidents of non-compliance referred to the full board, the Ethics Coordinator or designee documents the following in the GREB Meeting minutes: a description of the incident and findings,

verification of the non-compliance, GREB's decision, the remedial action required by GREB, the researchers' 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)
http://www.queensu.ca/secretariat/sites/webpublish.queensu.ca.uslclwww/files/files/policies/senateandtrustees/research_integrity.pdf

8.0 REVISION HISTORY

SOP Title	Version	Updates
Non-Compliance	v.903.001 2016MAR30	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.