Section 400	**Review of Research**
Title	**Non-Compliance**
SOP Code	**409.001**
Effective Date	**September 21, 2018**

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	Anthony Wright Digitally signed by Anthony Wright Date: 2018.10.05 12:07:20 -04'00'

1.0 PURPOSE

This standard operating procedure (SOP) describes the SLC-REB process for responding to reports of non-compliance and the actions that the SLC-REB may take as a result of its review of reports of serious and/or continuing non-compliance.

2.0 SCOPE

This SOP pertains to the SLC-REB and establishes its authority and jurisdiction to review human participant research conducted under the auspices of St. Lawrence College and ensure compliance with applicable regulations and guidelines. The scope of SLC-REB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants".

3.0 RESPONSIBILITIES

Research Services Officer, the SLC-REB Chair or designee, and researchers 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 approval of the SLC-REB.

The Research Services Officer and the SLC-REB members are responsible for acting on information or reports of non-compliance received from any source.

The SLC-REB Chair or designee is responsible for the initial review of allegations of noncompliance.

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

The SLC-REB Chair or designee is responsible for reporting any incidents of serious or continuing noncompliance to the researcher and to the appropriate organizational official(s), and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The SLC-REB may delegate regulatory authority reporting (as applicable) to an organizational official(s).

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Reports of non-compliance may come from any source including the SLC-REB 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 SLC-REB 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, 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;

5.1.2 Persons raising such concerns are encouraged to express them in writing. However, the Research Services Office will receive and document oral reports of noncompliance;

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 the SLC-REB, the Research Services Officer will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the SLC-REB Chair or designee;

5.2.2 The SLC-REB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;

5.2.3 The SLC-REB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegations;

5.2.4 The SLC-REB Chair or designee will obtain as much information as possible from the individual reporting the incident;

5.2.5 The SLC-REB Chair or designee 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 SLC-REB Chair or designee determines that there is evidence of noncompliance, they will then assess whether the non-compliance was intentional, serious and/or repeated;

5.2.7 If the SLC-REB Chair or designee 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 SLC-REB 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 SLC-REB Chair or designee 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 SLC-REB Chair or designee 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 SLC-REB Chair or designee may discuss the matter directly with the researcher, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the SLC-REB at a full board meeting;

5.3.4 If it appears that a researcher was intentionally non-compliant, the SLC-REB Chair or designee may suspend the conduct of the research immediately and refer the matter to the next full board meeting of the SLC-REB, and will inform the appropriate organizational official(s);

5.3.5 The SLC-REB 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 noncompliance. In evaluating the non-compliance, the SLC-REB may consider one or more of the following actions:

- Request modification of the protocol,
- Request modification of the informed consent document,
- 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 continuing review schedule,
- Require onsite observation of the consent process,
- Suspend the new enrollment of participants,
- Suspend SLC-REB approval of the research,
- Suspend researcher involvement in the research,
- Terminate SLC-REB approval 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 SLC-REB.

5.4 SLC-REB Response to Reports of Non-compliance

5.4.1 The SLC-REB Chair or designee will notify the researcher in writing of the results of the SLC-REB review of incidents of non-compliance and any remedial actions required;

5.4.2 The SLC-REB Chair or designee will report any serious or continuing non-compliance to the researcher as well as to the appropriate organizational official(s), and has the authority to report to the regulatory authorities (as applicable) and the sponsor. The SLC-REB may delegate regulatory authority reporting;

5.4.3 The SLC-REB may submit an allegation of research misconduct to St. Lawrence College official(s) as appropriate;

5.4.4 The SLC-REB will request a time-sensitive response in writing from the researcher, including the corrective action plan;

5.4.5 The researcher's response may be reviewed using a delegated SLC-REB review procedure or the review may be referred to the SLC-REB, for a decision from the full board;

5.4.6 The SLC-REB Chair or designee will follow-up to assess any corrective measures implemented by the researcher.

5.5 Documenting Non-compliance

5.5.1 The Research Services Officer will document the findings of reports of noncompliance. The report will including the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the SLC-REB'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 Research Services Officer will document the following in the SLC-REB meeting minutes: a description of the incident and findings, verification of the non-compliance, the SLC-REB's decision, the remedial action required by the SLC-REB, the researcher's response and actions implemented and plans for further follow-up.

6.0 REFERENCES

Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans; Tri-Agency Framework: Responsible Conduct of Research; SLC-Policy: Ethical Conduct of Research Involving Humans; SLC-Policy: Research Integrity.

7.0 REVISION HISTORY

SOP Title	Version	Updates
Non-Compliance	v.409.001 September 21, 2018	Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format.