



Section 400	Review of Research
Title	Research Requiring Federalwide Assurance (FWA)
SOP Code	410.001
Effective Date	September 21, 2018

Site Approvals

Signature of Responsible Individual:	
Research Services Officer	

1.0 PURPOSE

This standard operating procedure (SOP) describes the requirements for review, approval, and compliance of non-exempt research conducted, supported or otherwise subject to the U.S. Department of Health and Human Services (HHS) in accordance with Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects (also known as the Common Rule).

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 "non-exempt human subject research" supported or otherwise subject to U.S. federal departments or agencies regulated by the Common Rule.



3.0 RESPONSIBILITIES

The SLC-REB Chair, SLC-REB members tasked with reviewing research proposals for Federalwide Assurance (FWA) compliance, and the Human Protection Administrator (i.e., Research Services Officer) is responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.¹

Human Subject: means a living individual about whom an investigator (whether professional or student) conducting research obtains

- 1) Data through intervention or interaction with the individual, or
- 2) Identifiable private information²

5.0 PROCEDURE

The U.S. Office for Human Research Protection (OHRP) requires that all non-exempt research involving human subjects supported or otherwise subject to U.S. federal departments or agencies must be approved by an institution that has a registered Institutional Review Board (i.e., Research Ethics Board) that has been approved as a FWA IRB.

- St. Lawrence College Research Ethics Board IRB number is:
 - **IRB 00011647**
- St. Lawrence College Research Ethics Board FWA number is:

¹ Title 45 CFR 46.102(b);

² Ibid.



- **FWA 00027442**

5.1 Update or Renewal of SLC-REB Registration

- 5.1.1 The Research Services Officer is responsible for ensuring that all updates and renewals are reported to the U.S. Office of Human Protection (OHRP) in a timely manner;
- 5.1.2 Any updates or renewals must be reported using the electronic submission system available through the Electronic Submission System (ESS) on the [OHRP website](#);
- 5.1.3 SLC-REB registration updates must be made within ninety (90) days;
- 5.1.4 Any disbandment of the SLC-REB must be reported to OHRP in writing within thirty (30) days after the permanent cessation of the SLC-REB review of HHS supported or conducted research;
- 5.1.5 SLC-REB IRB registration is effective for three (3) years and must be renewed every three years, even if no changes have occurred, in order to maintain an active FWA;
- 5.1.6 Any renewal or update that is submitted and approved electronically will restart a new three-year period;
- 5.1.7 The FWA renewal/update is effective for five (5) years and must be renewed every five years, even if no changes have occurred, in order to maintain an active FWA. Any FWA renewal or update will require the Institutional Signatory Official's (i.e. President and CEO of SLC) approval. Any renewal or update that is submitted electronically, and approved by OHRP, begins a new five-year period.
- 5.1.8 The FWA Institutional Signatory Official must be authorized to represent and commit the entire institution and all of its components to a legally binding agreement.



1.1. Incident Reports

1.1.1. The Research Services Officer is responsible for sending incident reports to OHRP;

1.1.2. Incident reports may be related to the following:

- Unanticipated problems involving risks to research subjects or others,
- Serious Adverse Events (SAEs),
- Serious or continuing non-compliance with the Common Rule,
- Suspension or termination of SLC-REB ethics approval of a research project;

1.1.3. Additional guidance on reporting OHRP incidents can be found on the [OHRP website](#).

6.0 REFERENCES

- U.S. Department of Health and Human Services (HHS), Title 45, Code of Federal Regulations, Part 46, Protection of Human Subjects (also known as the Common Rule);
- Belmont Report (1979)
- Declaration of Helsinki (WMA)
- Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (2014); Tri-Agency Framework: Responsible Conduct of Research (2016); SLC-Policy: Ethical Conduct of Research Involving Humans (2017); SLC-Policy: Research Integrity (2017).

7.0 REVISION HISTORY

SOP Title	Version	Updates
Research Requiring Federalwide Assurance	v.410.001 September 21, 2018	Original