



# St. Lawrence College

**POLICY TITLE:** Ethical Research Involving Humans

**POLICY NUMBER:** CR501

**EFFECTIVE:** October 05, 2017

**APPROVED BY:** SLC Board of Governors

**REFERENCE:** Memorandum of Understanding: Roles and Responsibilities in the Management of Federal Grants and Awards (2008); Agreement on the Administration of Agency Grants and Awards by Research Institutions (2012); Interagency Advisory Panel on Research Ethics (PRE or Panel) *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) and any bona fide amendments from time to time found at found at URL:

<http://www.pre.ethics.gc.ca/eng/index/>

**LINKS TO OTHER POLICY:** SLC Research Integrity Policy CR502

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**Attachment:**

**Owner:** Applied Research

## **BACKGROUND**

In August 2006, the St. Lawrence College Research Ethics Board (SLC-REB) was instituted as a standing committee of St. Lawrence College (SLC or College).

The St Lawrence College's *Policy on Ethical Research Involving Humans* (ACR-2007-05-#002) and *Research Integrity Policy* (ACR-2007-05-#001) were approved by resolution by the SLC Board of Governors on May 08, 2007. The policies reflect the College's commitment to ensuring that the highest ethical standards in research is maintained at SLC in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS) and the *Tri-Agency Framework: Responsible Conduct of Research (RCR Framework)*.



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

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## **DEFINITIONS**

- Research - An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation

## **PURPOSE**

The purpose of this College's policy is to:

1. State the organizational authority under which the SLC-REB is established and empowered;
2. State reporting and administrative support;
3. State the management of the SLC-REB;
4. State the purpose of the SLC-REB;
5. State the principles governing the SLC-REB to ensure that the rights and welfare of participants are protected;
6. State the authority of the SLC-REB;
7. State researchers' right to reconsideration or appeal of SLC-REB decisions.

## **SCOPE:**

This policy pertains to all researchers conducting research involving human participants or human biological material that is conducted under the auspices of the College, irrespective of the source of financial support (if any) or the location of the project. This includes student course-based research (assigned for pedagogical or training purposes) that involves human participants (referred to as participants) and external researchers that wish to recruit participants or access resources at SLC.

The scope of the SLC-REB's oversight is limited to those activities defined in the TCPS as "research" involving "human participants."



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

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Owner: Applied Research

## POLICY STATEMENTS

The SLC-REB will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice, and ethics guidelines when reviewing proposed research.

### 1. Statement of Organizational Authority

- 1.1 The President and CEO invested in the SLC-REB the authority to review research involving human participants or human biological materials from living or deceased individuals, conducted within the jurisdiction or under the auspices of the College, in accordance with College policies, the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS)* and the *Tri-Agency Framework: Responsible Conduct of Research (RCR Framework)*.
- 1.2 The SLC-REB is established and empowered under the authority of St. Lawrence College. St. Lawrence College requires that all research involving participants be reviewed and approved by the SLC-REB prior to initiation of any research related activities.
- 1.3 St. Lawrence College maintains an arms-length relationship with the SLC-REB. While the SLC-REB is accountable to the SLC President and CEO through the Senior Vice-President, Academic, of St. Lawrence College for ensuring that the correct processes are followed for ethics review, it is independent in its decision-making. The administration of the College may not override negative SLC-REB decisions reached on grounds of non-compliance with research ethics. Similarly, the SLC-REB may not override SLC decisions to not allow certain research within its jurisdiction, even if the SLC-REB has found the research ethically acceptable.



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

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Owner: Applied Research

## 2. Reporting and Administrative Support

### 2.1 Reporting

The Research Services Officer reports to the Director, Innovations and Business Engagement. An annual report on the operation of the SLC-REB is submitted to St. Lawrence College through the Senior Vice-President, Academic.

### 2.2 Administration of the SLC-REB

St. Lawrence College is responsible for providing sufficient and ongoing financial and administrative resources to ensure that the SLC-REB can fulfill its mandate.

#### 2.2.1 Administrative Support

The work involved in the ethical review process shall be distributed appropriately among faculty members, staff, researchers, and administrators.

The Senior Vice-President, Academic, will rely on the Research Services Office in providing administrative support to the SLC-REB including:

- Distribution of forms and materials necessary for submission of research proposals to the SLC-REB,
- Collection of submissions and distribution of applications to SLC-REB members,
- Keeping minutes of SLC-REB meetings,
- Storing submissions and related materials in a secure location,
- Supporting the SLC-REB in its educational activities,



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

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**Owner: Applied Research**

- Acting as the point of contact for the Secretariat on Responsible Conduct of Research (SRCR), and liaison with other relevant agencies and REBs.
- Other duties related to the support of the SLC-REB in carrying out its mandate.

Deans will provide support to the SLC-REB, with respect to:

- Educational activities,
- Ensuring that researchers requiring ethical review are submitting their projects to the SLC-REB,
- Advising their faculty members about the need to comply with the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans*.

Individual Schools are expected to support and train students so that student research projects are ethical, and may be efficiently reviewed by the SLC-REB. Schools should establish a mechanism to screen student applications for ethical review prior to submission to the SLC-REB. The SLC-REB may return applications to the school if they do not conform to the requirements of the TCPS. It is advisable that curriculum committees consider incorporating training in the ethical review process into the academic programs where it is needed.

### **3. Management of the SLC-REB**

Individual members of the SLC-REB must be qualified through training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles, and applicable regulations, guidelines and standards pertaining to human participant protection.



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

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**Attachment:**

**Owner: Applied Research**

To promote complete and adequate review of the type of research commonly reviewed by the SLC-REB, the SLC-REB must include appropriate diversity; therefore, selection of members must include a consideration of professional expertise (including both scientific and non-scientific) to assess the research submitted for review. Important considerations are also race, sex, cultural backgrounds, clinical and research experience, organizational affiliation, and sensitivity to such issues as broad representation from organizations served by the SLC-REB.

## **3.1 Terms of Appointment**

- 3.1.1 The SLC-REB Chair is appointed by the Senior Vice-President, Academic, in consultation with the Director, Innovation and Business Engagement. The Chair should have at least two years of experience on the SLC-REB with knowledge of local policies and national regulations.
- 3.1.2 The Chair will serve for two years to allow for continuity of the research ethics review process. However, the term of appointment can be extended when a Chair possesses relevant and necessary expertise that would be difficult to replace;
- 3.1.3 Re-appointment of the SLC-REB Chair for an additional term will be by the Senior Vice-President, Academic, under the advice of the Director, Innovations and Business Development and agreement of the SLC-REB Chair;
- 3.1.4 The SLC-REB Chair can delegate his or her authority to a designee if the Chair has to recuse themselves or requires additional assistance when needed;
- 3.1.5 The Director, Innovations and Business Development, with advice from the Research Services Officer and the Chair, will seek new SLC-REB members through Department Heads, the SLC-REB Chair, and other SLC-REB members;



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

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**Owner: Applied Research**

- 3.1.6 SLC-REB membership is loosely connected to the number of applications received each year, such that some departments have more than one member, whereas other departments are grouped to provide a representative member.
- 3.1.7 Each SLC-REB member will serve for a three-year term to allow for continuity of the research ethics review process. However, the term of appointment can be extended when a member possesses relevant and necessary expertise that would be difficult to replace;
- 3.1.8 Re-appointment of a SLC-REB member for an additional term requires mutual agreement of the SLC-REB member and the SLC-REB Chair or designee;
- 3.1.9 The SLC-REB membership will be posted on the website and updated each time the membership is changed;
- 3.1.1.0 SLC-REB members' terms will be overlapping to preserve the experience level, expertise, and continuity of SLC-REB. To maintain continuity, SLC-REB will endeavor to have only one-third new members each year.

## **3.2 Selection of SLC-REB Members**

- 3.2.1 In selection of REB members, equal consideration shall be given to qualified persons regardless of gender.
- 3.2.2 The SLC-REB will make every effort to include cultural and ethnic minorities to represent the population from which research participants are recruited, within the scope of available expertise needed to conduct its functions;
- 3.2.3 The SLC-REB membership will not consist entirely of members of one discipline;



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

**Attachment:**

**Owner: Applied Research**

3.2.4 SLC-REB members will be selected based on the needs of the SLC-REB as outlined below and per applicable regulations, guidelines, and standards.

### **3.3 Composition of the SLC-REB**

3.3.1 The membership of the SLC-REB will be in compliance with the TCPS;

3.3.2 The SLC-REB Chair and the Research Services Officer monitors the SLC-REB membership composition and size based on types of applications SLC-REB receives and reviews, the number of reviews, and the necessary expertise required to adequately review submitted applications;

3.3.3 The SLC-REB will include at least five members represented by the following categories:

- At least two members who have expertise in relevant research disciplines, field and methodologies covered by the SLC-REB (for biomedical clinical trials, this will include at least one member who practices medicine or dentistry and who is in good standing with their regulatory body),
- At least one member who is primarily experienced in non-scientific disciplines,
- At least one member who is knowledgeable in ethics,
- At least one member who is knowledgeable in the relevant law. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research, and
- At least one community member who has no affiliation with the organization or the sponsor, and who is not part of the immediate family of a person who is affiliated with the organization;



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

**Attachment:**

**Owner: Applied Research**

- 3.3.4 A member may not fulfill more than two representative capacities or disciplines;
- 3.3.5 Members will include men and women, a majority of whom are Canadian citizens or permanent residents, and who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed research;
- 3.3.6 Membership, when required, should include at least one member who has expertise in complementary or alternative care or health research;
- 3.3.7 Additional membership as required by applicable legislation or guidelines.

## **3.4 Substitute Members**

- 3.4.1 The Senior Vice-President, Academic, in consultation with the Director, Innovations and Business Engagement, may appoint a substitute SLC-REB member so that the REB can continue to function when regular members are unable to attend due to illness or other unforeseen eventualities;
- 3.4.2 Substitute members should have the appropriate knowledge, expertise and training to contribute to the research ethics review process;
- 3.4.3 The minutes shall document when a substitute member replaces a primary SLC-REB member.

## **3.5 SLC-REB Chair**

- 3.5.1 Whenever possible and practicable, the SLC-REB Chair will be selected from experienced SLC-REB members who have expressed interest in becoming the SLC-REB Chair and who are familiar with the applicable regulations and guidance documents;



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

Attachment:

Owner: Applied Research

- 3.5.2 The Research Services Office Personnel updates the SLC-REB membership roster to reflect this change.

## 3.6 Ad Hoc Advisors

- 3.6.1 At his/her discretion, the SLC-REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the SLC-REB;
- 3.6.2 The ad hoc advisor may be asked to participate in the SLC-REB meeting to lend his/her expertise to the discussions;
- 3.6.3 All ad hoc advisors shall sign a *Confidentiality of Information and Conflict of Interest Agreement*;
- 3.6.4 The ad hoc advisor may not contribute directly to the SLC-REB's decision and their presence or absence shall not be used in establishing a quorum;
- 3.6.5 Documentation of key information provided by the ad hoc advisor shall be summarized in the SLC-REB minutes and if available, the written report shall be placed in the SLC-REB files.

## 3.7 Observers at SLC-REB Meetings

- 3.7.1 The SLC-REB may allow observers to attend its meetings;
- 3.7.2 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the SLC-REB conflict of interest and confidentiality procedures;



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

**Attachment:**

**Owner: Applied Research**

- 3.7.3 Where the SLC-REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion;
- 3.7.4 Observers shall not participate when the SLC-REB discusses its decision, reaches consensus or votes on the application;
- 3.7.5 The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

## **4. Purpose of the SLC-REB**

- 4.1 The SLC-REB's purpose is to protect the rights and welfare of human participants participating in research;
- 4.2 The SLC-REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection;
- 4.3 These include, but are not limited to, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), the Tri-Agency Framework: Responsible Conduct of Research (RCR Framework), and where applicable, Canadian Regulations.

## **5. Governing Principles**

The SLC-REB is guided by the ethical principles regarding all research involving human participants including:

- Respect for Persons:
  - Recognize the intrinsic value of human beings and the respect and consideration they are due,



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

**Attachment:**

**Owner: Applied Research**

- Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
  - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
  - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
  - Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - Obligation to treat people fairly with equal respect and concern,
  - Vulnerable or marginalized people may need to be afforded special attention.

## **6. SLC-REB Authority**

6.1 The SLC-REB is established to review all research involving human participants within its established jurisdiction;

6.2 The SLC-REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants. Specifically, the SLC-REB has the authority to:

- establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,
- approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction,
- ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants,



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

**Attachment:**

**Owner: Applied Research**

- request, receive and share any information involving the research that the SLC-REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy,
- conduct continuing ethical review to protect the rights and welfare and privacy of research participants,
- suspend or terminate the ethics approval for the research,
- place restrictions on the research,
- take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the SLC-REB's jurisdiction.

## **7. Reconsideration of SLC-REB Decisions**

Researchers have the right to request, and the SLC-REB has an obligation to provide, reconsideration of decisions affecting a research project.

- When the SLC-REB is considering a negative decision, it shall provide the researcher with all the reasons for the decision and give the researcher an opportunity to reply before making a final decision.
- SLC may not override SLC-REB decisions reached on grounds of ethics without a formal appeal mechanism.

## **8. Appeals**

Researchers must apply to the Senior Vice-President, Academic, to appeal a negative SLC-REB decision within two months of the date of the decision.

- A copy of the appeal letter should also be sent to the SLC-REB Chair.



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

---

**Attachment:**

**Owner: Applied Research**

- The College shall use a duly constituted REB at Algonquin College as its Appeal Board.
- Noncompliance with the current version of the TCPS is a reason for refusing to grant an appeal.
- Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS.
- The decision of the Appeal REB shall be final.

## **9. Sanctions**

The Senior Vice-President, Academic, shall have the sanction of refusing permission to open a research account or to access College controlled funds for researchers who do not comply with College policies, *The Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans*, or the *Tri-Agency Framework: Responsible Conduct of Research*.

The Research Services Officer or the SLC-REB Chair will report to the Director, Innovations and Business Engagement, any cases that undermine SLC's compliance with the Tri-Council's policies (TCPS, RCR Framework) and the Senior Vice-President, Academic, shall decide what sanctions or penalties to impose on the researcher(s) while respecting the collective agreement.



# St. Lawrence College

Policy on Ethical Conduct of Research Involving Humans [ CR501 ]

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Attachment:

Owner: Applied Research

## **MONITORING**

This policy will be reviewed and revised as needed but no less than every 5 years.

## **POLICY REVISION HISTORY**

- Previous version ACR-2007-05-#002, May 08, 2007

## **ACKNOWLEDGMENT**

This policy was developed based on information from the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* and St. Lawrence College's previous policies (using the format of the SLC Meta Policy, 2011).