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| Section 400 | Review of Research |
| Title | Review Decisions |
| SOP Code | 403.001 |
| Effective Date | June 13, 2018 |

Site Approvals

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| Signature of Responsible Individual: | |
| Research Services Officer | |

1.0 PURPOSE

This standard operating procedure (SOP) describes the decisions that the SLC-REB may make resulting from its review of proposed research for ethical acceptability.

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 Office personnel are responsible for ensuring that the requirements of this SOP are met.

The SLC-REB Chair or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the SLC-REB, that the decision is clearly



understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly agreed.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

As a result of its review, the SLC-REB has the authority to approve, disapprove, or to require modifications to submitted research. If there are questions that must be addressed prior to a determination, the SLC-REB may defer its decision. When the full board review procedure is used, decisions will be made by consensus or a majority vote of the SLC-REB members who are present at a full board meeting at which there is a quorum.

SLC-REB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the SLC-REB (if applicable), in accordance with the SLC-REB and St. Lawrence College's conflict of interest policies.

When the delegated review procedure is used, the SLC-REB Chair and/or SLC-REB member(s) who are assigned to the review can decide to approve the research or to request revisions to the research; the decision to disapprove the research must be made by the full board.

Researchers have the right to request reconsideration of the SLC-REB's decisions and to appeal the decision of the SLC-REB.

5.1 SLC-REB Decisions

5.1.1 SLC-REB decisions are made either by consensus or by a majority vote of the SLC-REB members present at a full board meeting, with the exception of

those who have recused themselves in accordance with the conflict of interest policies. The SLC-REB Chair abstains from voting except to break a tie vote;

5.1.2 The SLC-REB should reach one of the following decisions as a result of its review of research submitted for initial or for continuing review:

- **Approval**

Approve the application as submitted, including the consent form:

- When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted,
- The approval date is defined according to SLC-REB procedure,
- The expiry date of the SLC-REB approval is calculated from this date.

- **Approval with Recommendations:**

- When an acceptable risk/benefit ratio exists, and the regulatory criteria required for approval are satisfied, but the SLC-REB members require modification to any aspect of the application or clarification or further information to secure approval, the SLC-REB may recommend “Approval with Recommendations”,
- When the SLC-REB recommends “Approval with Recommendations”, the SLC-REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified at the SLC-REB meeting and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:



- The SLC-REB Chair alone,
 - The SLC-REB Chair and one or more named SLC-REB member(s) that were present at the SLC-REB meeting or who submitted written comments on the application,
 - A sub-group of the SLC-REB members designated by the SLC-REB Chair or designee or by the SLC-REB,
 - A designated SLC-REB member or members with sufficient knowledge and experience regarding the research and the regulations,
- In deciding the procedures to be followed, the SLC-REB should consider the significance of the requested additional information or modifications and the expertise necessary to assess it. Where the information or modifications are straightforward, it is acceptable to delegate the consideration of that material to the SLC-REB Chair or designee alone,
 - Where the additional information/modification is technical (e.g., statistical clarifications), the SLC-REB Chair or designee should review the information with consideration given to involving other SLC-REB members or relevant expert member(s),
 - If the researcher's response is deemed complete and satisfactory, approval can be issued,
 - If the researcher's response is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification should be sent to the researcher,
 - The reviewers may decide upon reviewing the researcher's response that the decision should be deferred and that the application and the researcher's response materials should be



reviewed at a subsequent full board meeting (see 'Deferral' process below),

- The approval date is defined according to the SLC-REB procedures. The expiry date of the SLC-REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met.

- **Deferral**

Defer decision-making on the application and continue the deliberation of the application at a future full board meeting:

- The SLC-REB will defer its decision to a subsequent full board meeting when significant questions are raised during its review of the research and/or when the criteria required for approval have not been met,
- The SLC-REB Chair or designee should ensure that all additional information, modifications or clarifications that are required are specifically identified at the full board meeting,
- The research and the researcher's response materials shall be reviewed at a full board meeting,
- Upon consideration of the research along with the response from the researcher, at the full board meeting, the SLC-REB should issue its final decision (approved, approved with modifications, deferral or disapproved),
- Researcher responses must be received and reviewed at a full board meeting. The approval date is defined according to the SLC-REB procedures. The expiry date of the SLC-REB approval is



calculated from this date, however, the approval letter is not issued until all the conditions for approval have been met.

- **Disapproval**

- The SLC-REB may disapprove the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the SLC-REB to reach a positive determination,
- Disapproval cannot be decided through the delegated review mechanism. If the recommendation under delegated review is to disapprove the research, a final decision must be made by the SLC-REB at a full board meeting,
- The SLC-REB Chair or designee should ensure that the reasons for the disapproval are identified at the full board meeting for communication to the researcher,
- If the research is disapproved, the reasons for disapproval will be communicated to the researcher and the researcher will be given an opportunity to respond in person or in writing.

5.2 Delegated Reviews

5.2.1 When the research qualifies for delegated review, the reviewer(s) has the authority to approve the application, to require modifications to any aspect of the application, or to request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a full board meeting,

5.2.2 When delegated review procedures are followed, approval is considered as the day the research is approved by the SLC-REB Chair or designee as well as all other designated reviewer(s), if applicable. The expiry date of the SLC-



REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met,

- 5.2.3 If the research cannot be approved through the delegated review mechanism, it must be reviewed at a full board meeting.

5.3 Reconsideration and Appeal of SLC-REB Decisions

- 5.3.1 A researcher may appeal the decision of the SLC-REB if the disagreement between the researcher and the SLC-REB cannot be resolved through a reconsideration process at a full board meeting at which the researcher shall have the right to be heard;
- 5.3.2 The researcher must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons and a final decision after reconsideration must be issued by the SLC-REB prior to the initiation of an appeal process;
- 5.3.3 Appeals are conducted in accordance with the St. Lawrence College policy: *Ethical Conduct of Research Involving Humans*. The Appeal REB used by St. Lawrence College is Georgian College's REB. Georgian College's REB will come to its determination on a case-by-case basis in consultation with the researcher and St. Lawrence College;
- 5.3.4 Georgian College's REB shall have the authority to review negative decisions made by the SLC-REB and in so doing it may approve, disapprove or request modifications to the research proposal. Its decision shall be final and shall be communicated to the researcher and the SLC-REB in writing.

5.4 Documenting SLC-REB Decisions

- 5.4.1 The SLC-REB meeting minutes will satisfy the applicable requirements;
- 5.4.2 The SLC-REB shall notify the researcher in writing of its decision to approve or disapprove the proposed research, or of any modifications/clarifications required to secure approval of the research;



- 5.4.3 If the SLC-REB defers its decision, the letter to the researcher should include the issues of concern and what further information is required;
- 5.4.4 The final approval letter should include standard conditions of approval to which the Researcher must adhere;
- 5.4.5 When the decision to approve a submission is recorded on behalf of the full board or when a delegated reviewer electronically signs off on a decision (under delegated review procedures), the notification, or correspondence to the researcher, may be issued by the Research Services Office personnel.

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 |
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| Review Decisions | v.403.001 Jun 13, 2018 | Original: This SOP was developed based on previous SLC policies and the TCPS using the CAREB/N2 standardized REB SOP format. |
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