

SOP 1-01: Risk Assessment, Determining Level of Review, and Review Procedures

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedures for screening new applications submitted to Wilfrid Laurier University’s Research Ethics Board (REB). This includes assessing the risk level associated with the research, determining the appropriate level of review, and describing the procedures associated with each level of review. This SOP is guided by the principle of proportionate review outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2).

2. Scope

This SOP applies to all research ethics applications submitted to the REB at Wilfrid Laurier University.

3. Definitions

- Risk: A function of the magnitude or seriousness of potential harm, and the probability that it will occur, whether to participants or to third parties ([TCPS2 Ch2B](#)).

- Risk Assessment: The process of identifying and evaluating potential harms associated with a research ethics proposal in light of the research design, participant context, and proposed safeguards.
- Minimal Risk Research: Research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research ([TCPS2 Ch2B](#)).
- Higher-Than-Minimal-Risk Research: Research in which the probability and magnitude of possible harms implied by participation in the research are greater than those encountered by participants in those aspects of their everyday life that relate to the research.
- Delegated Review: The level of REB review assigned to minimal-risk research projects. Typically, this level of review is conducted by one REB member (or the Research Ethics Coordinator, Psychology (RECP)), a Co-Chair, and where applicable, an REB administrator.
- Delegated Subcommittee Review: The level of REB review assigned to research that does not meet the threshold for higher-than-minimal-risk and full board review but does require a higher level of scrutiny. This level of review is conducted by a selected group of 3-4 reviewers including a Co-Chair.
- Full Board Review: The level of REB review assigned to higher-than-minimal risk research projects. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving humans ([TCPS2 Article 6.12](#)).

4. Procedure

4.1 Initial Screening

Upon submission of a research application to the REB, the Research Ethics Officer (REO) or the RECP will conduct an initial screening to ensure the application is complete and all necessary documents are included. Incomplete submissions will be returned to the researcher for completion.

4.2 Risk Assessment

Upon the receipt of a complete research application, an administrator (either the REO or RECP) will perform a preliminary risk assessment to categorize the proposal as minimal-risk or higher-than-minimal-risk. In keeping with [TCPS2 Article 2.10](#), care will be taken not to compound research-attributable risks with other risks to which participants are exposed.

The following factors will be considered when determining the level of risk of a protocol:

Research Risk

Refers to the potential harm that may arise from the design, methods, procedures, or

Participant/Group Vulnerability

Refers to any pre-existing characteristics or circumstances that may reduce participants' ability to freely consent or

conduct of the research itself, regardless of the characteristics of the participants

- Potential types of harm arising from participation (psychological/emotional, social, legal, physical, etc.)
- Potential risks to the communities the participants are from resulting from the conduct or dissemination of the research
- Researcher experience and training, as they relate to the safe and ethical conduct of the research
- Nature and sensitivity of the research questions and tasks
- Privacy and confidentiality measures or identifiability of participants
- Researcher/institution conflicts of interest

may increase their susceptibility to harm in the context of the research

- Participant age
- Participant decision-making capacity
- Physical, psychological, or economic circumstances that may make participants vulnerable in the context of research
- Resources available to individuals after their participation
- Power imbalances or dependency relationships

Magnitude of Potential Harm

- How damaging the harm has the potential to be to participants and the groups the participants are from

Probability of Potential Harm

- How likely the protocol is to cause harm to participants and the groups the participants are from

Based on consideration of the factors outlined above, if there is the reasonable belief that the probability and magnitude of possible harms incurred by participation in the research are greater than those encountered by participants in their everyday life, the application is considered **higher-than-minimal risk**. Otherwise, it is considered **minimal-risk**.

4.3 Deciding Level of Review

There are three procedural tiers of REB review at Wilfrid Laurier University: delegated review, delegated subcommittee review, and full Board review. Delegated review and delegated subcommittee review are both forms of delegated review for minimal-risk research under TCPS2, while full Board review applies to higher-than-minimal-risk research. The level of review assigned to a project is determined using a proportionality-based and context-sensitive approach, informed by the risk-assessment outlined in Section 4.2.

In determining the appropriate level of review, the reviewing administrator, in consultation with the REB Co-Chair, will consider:

- The assessed level of risk, including the magnitude and probability of potential harms, as outlined through the risk assessment process
- The degree of participant or group vulnerability in the research context
- The complexity and sensitivity of the ethical issues raised by the study, and the expertise required to adequately assess them, including review by multiple REB members or consultation with external experts would be beneficial to support a proportionate assessment
- The knowledge, training and experience of the research team relative to the level of risk and the proposed research methods.
- Relevant REB precedent involving similar protocols or methodologies.

Where research is assessed as minimal risk, but one or more of the considerations above suggest that additional perspectives or deliberation would assist in the review, the application may be assigned to delegated subcommittee review. Research that is assessed as higher-than-minimal risk will be reviewed by the full REB, in accordance with TCPS2.

Table 1: Matrix with suggestions for level of review based on research risk and participant/group vulnerability

Participant/Group Vulnerability	Research Risk		
	Low	Medium	High
Low	Delegated	Delegated	Delegated Subcommittee or Full Board
Medium	Delegated	Delegated or subcommittee	Full Board
High	Subcommittee or Full Board	Full Board	Full Board

Note: The matrix is intended as a decision-support guide only and does not replace REB judgment or discretion in assigning the appropriate level of review. Research risk reflected in the table incorporates consideration of the probability and magnitude of potential harms, as assessed in Section 4.2.

4.3.1 Additional Considerations for Delegated Subcommittee Review

Research that is assessed as minimal-risk is typically eligible for delegated review. In some instances, a project may not meet the threshold for higher-than-minimal-risk but may raise additional considerations that warrant enhanced scrutiny within delegated review. In such cases, the application may be assigned to delegated subcommittee review. Delegated subcommittee review is used to support proportionate, context-sensitive review of minimal-risk research where additional perspectives, deliberation, or expertise would assist in adequately assessing the ethical acceptability of the project.

Factors that may support assignment to delegated subcommittee review include:

- multiple or interacting low-level risks
- uncertainty regarding the likelihood or potential impact of harms
- contextual participant or group vulnerability that warrants closer consideration
- sensitivity of the research topic, questions, or data being collected
- novel, emerging, or less familiar methodologies
- the need for additional disciplinary or methodological expertise

4.3.2 Procedure for Delegated Review

If an application is deemed minimal-risk, it will be sent for delegated review. It will be reviewed by a member of the REB (or the RECP), the appropriate Co-Chair, and in the case of non-psychology applications, an administrator.

4.3.3 Procedure for Delegated Subcommittee Review

If an application does not meet the threshold for higher-than-minimal-risk and full board review, but does require a higher level of scrutiny, it will be reviewed by subcommittee.

- A subcommittee of 3-4 REB members will be assigned to review the application by the REO. In the case of Psychology applications, the subcommittee will also contain the RECP.
- The subcommittee will be given one week to submit their comments on the application.
- The REO will compile the comments from all reviewers into a memo and send it back to the subcommittee members to ensure that their concerns are addressed.
- When everyone has provided their feedback, the memo will be sent to the research team on Romeo within two business days.

4.3.4 Procedure for Full Board Review

If an application is determined to be higher-than-minimal risk, it will be reviewed by the full Board.

- The research team will be notified that their project is higher-than-minimal risk and requires a review by the Full Board.
- A lead Board review team, consisting of the REO, two or more REB members, and the Co-Chair responsible for the application, will be convened to conduct a focused, initial review to support full board deliberation. The memo that results from this review will be presented for discussion during the full board meeting as described below.
- A full board review meeting will be scheduled by the REO for 4-5 weeks from the initial receipt of the application. All members will be assigned to the application in Romeo and invited to submit comments within 2 weeks.
- One week ahead of the full Board meeting, the REO will compile the comments provided by the lead review team into an initial memo.

- The full Board will discuss the proposal and initial memo during the convened meeting.
 - The Co-Chair will lead a short discussion of the application and the compiled comments from the lead Board review team. This discussion will focus on the major comments and concerns raised by the lead Board review team and the expectations for approval.
 - The Board will approve the list of comments by consensus or, if necessary, by majority vote. They will also approve the conditions of approval.
- This memo will typically be sent to the research team on Romeo within two business days of the meeting.
- Should the research team require any further clarification or justification of the memo items, the REO will meet with the Co-Chair and the research team to discuss the initial memo.
- The REO will review the resubmission of a higher-than-minimal risk protocol upon receipt.
- If the resubmission addresses the Board’s comments and adheres to the expectations of approval, the REO will issue approval.
- If there are any outstanding concerns or comments identified in the resubmission review, the administrator will send an additional memo to the researchers for further revisions.
- If the administrator requires further confirmation that a comment has been addressed satisfactorily, they will reach out to the REB member who initially made the comment to ask if it has been answered appropriately.

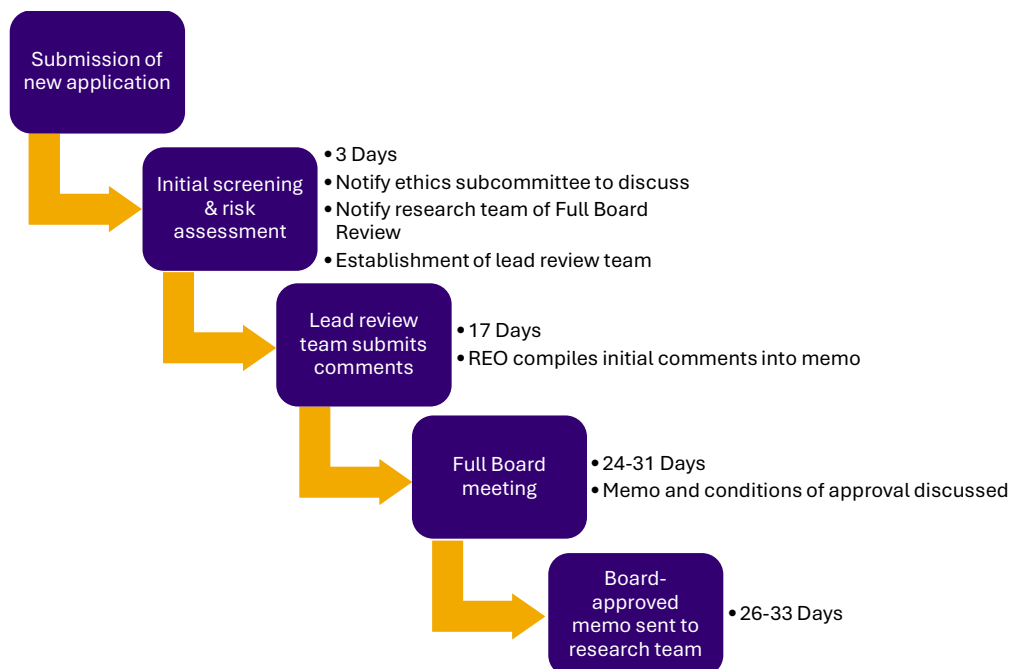


Figure 1: Full board application review timeline

4.3.5 Procedure for Expert Review

Where the REB does not collectively possess sufficient expertise to adequately assess specific aspects of a research application under review, the REB may seek advice from one or more independent external experts to inform its review. Expert review may be used to support delegated review (including delegated subcommittee review) or full Board review, as appropriate. External expert input is advisory in nature and does not replace REB review or decision-making authority, which remains the responsibility of the REB. Please see [REB_SOP – Review of Higher Risk Procedures](#) for a detailed description of the procedure.