

Guideline #: 003 – 2024

Title: **Guideline for the Review of More than Minimal Risk Projects**

## **1. Purpose**

This document describes the process for the Lakehead University Research Ethics Board (REB) to follow for reviewing all Full Board review projects.

## **2. Definitions**

*Delegated review:* “The level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership, with the exception of the ethics review of minimal risk student course-based research activities, which can be reviewed by delegates from the student's department, faculty, or an equivalent level” (TCPS-2 2022).

*Full board review:* “The level of REB review assigned to above 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” (TCPS-2 2022).

*Minimal risk to participants:* “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” (TCPS-2 2022).

*More than minimal risk to participants:* Research in which the probability and/or magnitude of possible harms implied by participation in the research is greater than those encountered by participants in those aspects of their everyday life that relate to the research.

*Proportionate approach to research ethics review:* “The assessment of foreseeable risk to determine the level of scrutiny a research proposal will receive (i.e., delegated review for minimal risk research or full research ethics board review for research above minimal risk), as well as the consideration of the foreseeable risks, the potential benefits, and the ethical implications of the research in the context of initial and continuing review” (TCPS-2 2022).

## **3. Determination of adequate relevant expertise**

An initial determination regarding whether the REB has sufficient representation and expertise to be able to assess the ethical compliance of all aspects of the proposed research should be made early in the review process, e.g. during Research Office pre-

screening (in consultation with REB Chair as needed). If at any point during the review of a project any reviewer or REB member does not believe that adequate expertise is represented within the REB to be able to assess the proposed research, they should inform the REB Chair as soon as possible, in case assistance from an *ad hoc* reviewer is needed.

#### **4. Determination of more than minimal risk**

Projects requiring Full Board review are those projects that are deemed to be more than minimal risk to participants, and those projects that do not clearly pose only minimal risk to participants. The [Guideline for Researchers and the REB # 001 13-14 “Eligibility for Delegated Review: Minimal Risk Criteria”](#) explains the process for determining whether a research project is a minimal risk project or one that is more than minimal risk, and thus for assigning projects to either delegated review or to Full Board review.

If at any point during the delegated review process any reviewer believes that the project being reviewed poses more than minimal risk, or that it is unclear whether the project poses more than minimal risk, they should notify the REB Chair as soon as possible. In such cases, the project is to be re-assigned to the Full Board review process. Thus, all reviewers are encouraged to make this determination as soon as possible, and avoid leaving such a determination until the end of the allotted timeframe for delegated review.

TCPS-2 2022, 6.12: “Delegated reviewers may call on other reviewers within the REB or refer projects back to the full REB if they determine that full board review is required”.

#### **5. Process for Full Board project review**

5.1 A project is deemed to be more than minimal risk, or not clearly minimal risk.

5.2 The Research ethics office makes the project available to all REB members via ROMEo portal.

5.3 Declaration of Conflict of Interest (COI): REB members should swiftly declare to the REB Chair if they have a potential, actual or perceived conflict of interest in executing their review of the project. (See TCPS-2 Chapter 7: Conflict of Interest, section C “Research Ethics Board Members and Conflicts of Interest”, Article 7.3).

5.4 In the context Full Board review, no comments or questions from the REB should be communicated to the researcher(s) until after Full Board discussion of the project. While all reviewer comments and questions should be considered by the REB, only those agreed upon by the REB should be forwarded to the researcher for response.

5.5 The research project is placed as an item on the agenda for the next scheduled REB meeting. If there is no scheduled upcoming REB meeting, then one should be convened.

5.6 The researcher is invited to attend the next scheduled REB meeting, where the project will be set as an item on the agenda for discussion.

5.7 Prior to the meeting where the project is to be discussed, all REB members have opportunity to review and to provide suggested comments and questions via the ROMEo portal. Questions and comments received via ROMEo are to be amalgamated by the Research Ethics Office (in consultation with REB Chair, as needed).

5.8 During the REB meeting where the project is discussed, the researcher is asked to briefly present their research protocol, and the REB then asks prepared questions of the researcher, and additional questions for clarification as necessary.

5.9 After the researcher has left the meeting, the REB discusses the project. REB deliberation should be focused on whether the project meets the ethical standards outlined in the TCPS-2. **Note:** Ideally, the review process should not include more than one round of new questions or comments from the REB to the researcher, unless new issues or concerns arise in light of researcher response to subsequent questions. Any subsequent round of new questions for Full Board projects ought to first be approved by the REB, before sending to the researcher. Some explanation to the researcher may be required.

5.10 The REB makes a decision. Possible outcomes of REB deliberation:

- A. **Decision not to provide ethics approval** for the proposed research. “Where the REB denies ethics approval for a research proposal, the minutes shall include the reasons for this decision” (TCPS-2 2022, 6.17). Reasons for denying ethics approval should be clearly stated and grounded in failure of the research project to meet the ethical principles of respect for persons, concern for welfare, and/or justice, in some way.
- B. **Decision to defer decision.** Possible reasons for this decision include e.g. to because more information is required, or because proper quorum has not been achieved, etc. Clear reasons/justifications for making this decision are needed.
- C. **Decision to provide conditional ethics approval**, pending subsequent changes to the research protocol and/or its participant materials made by the researcher, or similar.

- D. **Decision to provide ethics approval** for the project without any substantive changes needed.

5.11 Depending on the choice made at 5.10, the REB discusses and approves additional questions for the researcher, and a list of changes to be made to the research protocol, which are to be forwarded to the researcher thereafter.

5.12 The REB determines whether follow up actions may be approved by the REB Chair, a delegated review process, or else that Full Board Review is required. If Full Board review is required, then the REB decision about the project subsequent to researcher responses would typically come to the next scheduled REB meeting for discussion and approval.

## **6. Decision making during Full Board review**

6.1 Quorum is required: see Lakehead University Research Ethics Board (REB) Terms of Reference (2021), and TCPS-2.

6.2 If the researcher has declined the invitation to attend the REB meeting where the Full Board project is discussed: Prior to REB's deliberation at the meeting where a decision is being made on a Full Board review project, the researcher should have had opportunity to respond to all REB-approved questions. Researcher responses to REB questions should be made available to all REB members prior to the Full Board review meeting with sufficient time to provide reasonable opportunity to review.

6.3 If an *ad hoc* reviewer has been consulted on a project, their review and comments should be made available to all REB members reviewing the project, with sufficient time to provide reasonable opportunity to review.

## **7. Voting**

The voting process to be followed for Full Board review projects is the same as outlined in the Lakehead University REB Terms of Reference (2021). The voting process should allow opportunity for any opposition and abstentions to be heard and noted.

While REB decisions regarding Full Board review projects do not need to be unanimous, a consensus should be sought where possible. The REB should consider possible modifications to the research project that may help to generate consensus, where appropriate. If a consensus is not reached, then the decision is to be reached via majority vote.

## **8. Related documents**

- 8.1 [Terms of Reference for Research Ethics Board \(REB\)](#)
- 8.2 [Guideline for Researchers and the REB # 001 13-14 “Eligibility for Delegated Review: Minimal Risk Criteria”](#)
- 8.3 [N2 CAREB SOP 302.003 REB Meeting Administration](#)
- 8.4 [TCPS-2 \(2022\)](#)