SOP Title	NMREB Review Decision
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance	Erika Basile	Mar 3, 2025
Dr. Isha DeCoito Chair, Non-Medical Research Ethics Board	Isha DeCoito	Mar 3, 2025

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the decision that the University of Western Ontario's Non-Medical Research Ethics Board (NMREB) may make resulting from its review of a submitted research proposal.

2. GENERAL POLICY STATEMENT

2.1. As a result of the review, the NMREB 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 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 REB members who are present at a Full Board meeting at which there is a quorum;

2.2. NMREB members with a conflict of interest in the research under review may be present to answer any questions the Board may have with regard to the research proposal but they must not be present during the deliberations and the vote;

2.3. When the delegated review procedure is used, the NMREB Chair, Vice Chair(s) and/or NMREB member(s) who are assigned to review the research proposal can decide to approve (as submitted or with conditions) or defer to Full Board. A delegated study cannot be rejected. This can only be determined by the Full Board;

2.4. Investigators have the right to request reconsideration of the NMREB's decisions and to appeal the decision.

3. RESPONSIBILITY

This SOP is applicable to the Office of Human Research Ethics (OHRE), NMREB Chair, Vice-chair(s) and NMREB members;

The NMREB Chair or Vice- Chair(s) is responsible for ensuring that a decision is made for every submission that is reviewed by the NMREB, and that the decision is clearly understood. Investigators will be made aware, in writing (including electronic), of the decision. The delegation of responsibility for considering any further information prior to issuing approval will also be clearly understood.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. The Application Process

5.1.1. The OHRE will review each submission for completeness. If there are elements from the submission missing, the Investigator will be notified.

5.1.2. **Review Procedures**

5.1.2.1. Initial submissions are pre-screened for completeness and assessment of the level of risk. If the application will be reviewed at the Full Board level, it will be reviewed in accordance with the following procedures:

5.1.2.1.1. The Ethics Officer (EO), in consultation with the NMREB Chair as necessary, will assign the research proposal to one primary reviewer;

5.1.2.1.2. All materials and relevant documents will be accessible to all NMREB members on the online system. All NMREB members will receive an email notification approximately 7 days prior to the NMREB meeting at which the study is scheduled to be reviewed;

5.1.2.1.3. Discussion of the research proposal at the NMREB meeting will be led by the primary reviewer. If the primary reviewer is absent from the meeting at which the study will be reviewed, the discussion will be led by the NMREB Chair, Vice Chair, or designee, or the application will be removed from the agenda and discussed at the next meeting.

5.2. NMREB Decision

5.2.1. The NMREB decision is made by all NMREB members who are present at the convened meeting, with the exception of those who have a conflict of interest;

5.2.2. The NMREB will reach one of the following decisions as a result of its review of a research proposal submitted for initial or for continuing review:

5.2.2.1. Approves research without conditions

5.2.2.1.1. When an acceptable risk/benefit ratio exists and the submission does not require changes to the protocol or accompanying documents, the research proposal may be approved as submitted;

5.2.2.1.2. The initial approval date will be set as the meeting date;

5.2.2.1.3. The date by which continuing review must occur will be 1 year from the initial approval date (e.g., if the approval date is Feb 1, 2013. The date by which continuing review must occur is no later than Feb 1, 2014).

5.2.2.2. Approves research with conditions

5.2.2.2.1. When an acceptable risk/benefit ratio exists but the submission requires changes to the protocol or accompanying documents, the research proposal may be approved with conditions;

5.2.2.2.2. The NMREB Chair or Vice Chair should ensure that the additional information, modifications or clarifications required are identified at the meeting and written Recommendations for additional information, modifications or clarifications is sent to the Investigator by the NMREB Chair or Vice Chair through the EO;

5.2.2.2.3. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:

- The NMREB Chair or Vice Chair alone;
- The NMREB Chair or Vice Chair and one or more named NMREB members that were present at the meeting;
- A designated NMREB member or members with sufficient knowledge and expertise regarding the research proposal and the regulations;

5.2.2.2.4. If the Investigator's response to the Recommendations issued by the NMREB is deemed complete and satisfactory, approval can be issued;

5.2.2.2.5. If the Investigator's response is incomplete further Recommendations for additional information, modifications or clarifications will be sent to the Investigator;

5.2.2.2.6. The effective date of the initial approval is the date on which the NMREB Chair or Vice Chair has reviewed and accepted all changes to the protocol and supporting documents;

5.2.2.2.7. The date by which continuing review must occur will be 1 year from the initial approval date (e.g., if the approval date is Feb 1, 2013. The date by which continuing review must occur is no later than Feb 1, 2014).

5.2.2.3. Deferral (defer a decision on the application and continue the deliberation of the application at a future meeting):

5.2.2.3.1. The NMREB will defer its decision to a subsequent meeting when the research proposal does not have sufficient information to arrive at a determination, or if the NMREB requires extensive revisions to any part of the research proposal;

5.2.2.3.2. The NMREB Chair or Vice Chair should ensure that the additional information, modifications or clarifications required are identified at the meeting and written Recommendations for additional information, modifications or clarifications is sent to the Investigator by the Chair or Vice Chair through the EO;

5.2.2.3.3. The Investigator's response to the Recommendations issued by the NMREB shall be reviewed at a convened meeting;

5.2.2.3.4. Upon consideration of the research proposal along with the response from the Investigator, at the meeting, the NMREB should issue its final decision (approved (as submitted or with conditions), deferred or disapproved);

5.2.2.3.5. If the Investigator's response to the Recommendations issued by the NMREB is deemed complete and satisfactory, approval can be issued;

5.2.2.3.6. If the Investigator's response is incomplete further Recommendations for additional information, modifications or clarifications should be sent to the Investigator;

5.2.2.3.7. The effective date of the initial approval is the date on which the NMREB Chair or Vice Chair has reviewed and accepted all changes to the protocol and supporting documents;

5.2.2.3.8. The date by which continuing review must occur will be 1 year from the initial approval date (e.g., if the approval date is Feb 1, 2013. The date by which continuing review must occur is no later than Feb 1, 2014).

5.2.2.4. Disapproval

5.2.2.4.1. The NMREB may disapprove a research proposal when it fails to meet the ethical standards for approval and where revisions are unlikely to enable the NMREB to research a positive determination;

5.2.2.4.2. Disapproval cannot be decided through the delegated review process. If the Recommendations under delegated review is to disapprove the research proposal, a final decision must be made by the Full Board at a convened meeting;

5.2.2.4.3. The REB Chair or designee should ensure that the reasons for the disapproval are identified at the Full Board meeting for communication to the Investigator;

5.2.2.4.4. If the research proposal is disapproved, the reasons for disapproval will be communicated to the Investigator and the Investigator will be given the opportunity to respond in person or in writing.

5.3. Reconsideration and Appeal of NMREB Decisions

5.3.1. An Investigator may appeal the decision of the NMREB if the disagreement between the Investigator and Board cannot be resolved through a reconsideration process at a convened meeting of the NMREB at which the Investigator shall have the right to be heard;

5.3.2. The Investigator must justify the grounds on which a reconsideration of the decision is requested. A reconsideration, may be launched only for procedural or substantive reasons, and a final decision after reconsideration must be issued by the NMREB prior to the initiation of an appeal process;

5.3.3. Appeals are conducted in accordance with the established institutional policy and the process is documented in a formal agreement;

5.3.4. The appeal committee shall have the authority to review negative decisions made by the NMREB 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 Investigator and the NMREB in writing.

5.4. Documenting NMREB Decisions

5.4.1. For each project, the responsible EO should ensure that the meeting minutes record the following:

- The decision made by the NMREB,
- The vote on those decisions, including the number of members voting for or against and the number abstaining,
- The members recused due to conflicts of interest,
- A summary of the discussion

5.4.2. The NMREB shall notify the Investigator in writing (including electronic) of its decision to approve or disapprove the proposed research or of modifications required to secure approval of the research;

5.4.3. If the NMREB defers its decision, the letter to the Investigator 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 Investigator must adhere;

5.4.5. When the decision to approve a submission is recorded on behalf of the full Board or by an expedited reviewer, the notification or correspondence to the Investigator may be issued by the EO.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
6.2. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.109, 46.111

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
N403.001	Original	07/07/2016
N403.002	Administrative Revisions	05/11/2018
N403.003	Update to NMREB Chair, Removal of Sections 2.2 and 5.2.2.3.5, Addition of Section 5.2.2.4.3; and Administrative Corrections	03/03/2025