TITLE	**401: HREB Review Decisions**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

1.0 PURPOSE

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

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITY

HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

The HREB Chairperson or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the HREB, that the decision is clearly communicated, and that the delegation of responsibility for considering any further information prior to issuing approval is determined.

4.0 PROCEDURE

The HREB has the authority to approve, approve pending changes, or refuse to approve research, submitted for its review. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the HREB members, at a duly constituted Full Board meeting.

When the delegated review procedure is used, the HREB Chairperson and/or delegated reviewer(s) assigned to the review can decide to approve the research or to approve the research subject to changes; the decision to refuse to approve the research must be made by the Full Board.

Researchers have the right to request reconsideration of the HREB decisions and to appeal the decision of the HREB.

HREB members with a conflict of interest in the research under review must not participate in the deliberations or in the vote of the HREB (if applicable), in accordance with the HREA conflict of interest policy and SOPs.

4.1 HREB Decisions

- **4.1.1** HREB decisions are made either by consensus or a majority vote of the HREB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies. For research subject to the US Code of Federal Regulations, quorum shall also include a majority (50%+1) of voting members.

4.1.2 The HREB shall reach one of the following decisions as a result of its review of research submitted for initial or for continuing review within 30 days of receiving the completed application:

- **Approve** (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.
  - For studies reviewed by the Full Board, the approval date is defined according to the date of the Full Board HREB meeting review. This date is provided in the HREB approval letter.
  - For studies reviewed via delegated review, the approval date is defined according to the date the HREB Chairperson or designee confirms approval. This date is provided in the HREB approval letter.
  - The expiry date of the HREB approval is calculated from the approval date.

- **Approve Subject to Changes:**
  - When an acceptable risk/benefit ratio exists, and the regulatory criteria required for approval are satisfied, but the HREB members require modification to any aspect of the application or clarification or further information to secure approval, the HREB may recommend "Approval Subject to Changes."
  - A written explanation of the conditions and/or modifications is sent to the Researcher by the Chairperson of the HREB through the REO Personnel.
  - When the HREB recommends "Approval Subject to Changes", the HREB Chairperson or designee will ensure that the additional information, modifications, or clarifications required are identified at the HREB 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 will be delegated to one of the following:
    - the HREB Chairperson alone;
    - the HREB Chairperson and one or more named HREB members that were present at the HREB meeting or who submitted written comments on the application;
    - a sub-group of the HREB members designated by the HREB Chairperson or designee or by the HREB; or
    - a designated HREB member or members with appropriate knowledge and experience regarding the research and the regulations.
  - In deciding the procedures to be followed, the HREB will consider the significance of the requested additional information or modifications and the expertise necessary to assess

it. Where the information or modifications are explicit and clearly identified, it is acceptable to delegate the consideration of that material to the HREB Chairperson or designee alone.

- Where the additional information/modification is technical (e.g., statistical clarifications), the HREB Chairperson or designee should review the information with consideration given to involving other HREB members, such as the lead reviewer(s) 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 will be sent to the Researcher.
- The reviewers may decide upon reviewing the Researcher's response that the Researcher's response materials will be considered at the subsequent Full Board meeting, in keeping with the meeting deadline schedule. The Researcher may be invited to meet with the reviewer, HREB Chair or the HREB meeting to provide information regarding the study.
- The approval date is defined according to the date the HREB Chairperson or designee or the Full Board confirms approval. This date is provided in the HREB approval letter. The expiry date of the HREB approval is calculated from this date.
- A final decision to refuse to approve the research, must be made by the HREB at a Full Board meeting.

- **Refuse to Approve**
  - The HREB may refuse to approve the research when it fails to meet the ethical standards for approval and where revision is unlikely to enable the HREB to reach a positive determination.
  - Refusal to approve cannot be decided through the delegated review process. If the recommendation under delegated review is to refuse to approve the research, a final decision must be made by the HREB at a Full Board meeting.
  - The HREB Chairperson or designee will ensure that the reasons for the refusal to approve are identified at the Full Board meeting for communication to the Researcher.
  - If the research is refused to be approved, the reasons for refusal to approve will be communicated to the Researcher and the Researcher will be given an opportunity to respond in person or in writing.

4.1.3 Delegated Reviews:

- When the research qualifies for delegated review, the reviewer(s) has the authority to approve, or approve the application subject to changes. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting. A decision to approve or approve the application subject to changes must be made within 30 days of the HREB receiving the completed application.
- When delegated review procedures are followed, approval is considered as the day the research is approved by the HREB Chairperson or designee as well, as all other designated reviewer(s), if applicable. The expiry date of the HREB approval is calculated

from this date and is provided in the HREB approval letter. The approval letter is not issued until all of the conditions for approval have been met.

- If the research cannot be approved through the delegated review mechanism, it must be reviewed at a Full Board meeting within 30 days of the HREB receiving the completed application.

4.2 Reconsideration of HREB Decisions

4.2.1 A Researcher may request that the HREB reconsider a review decision by submitting a letter to the HREB. The Researcher may present its submission in writing and/or in person at an HREB meeting. The Researcher may provide additional information for the HREB's consideration.

4.2.2 The HREB shall initiate and conduct a review of its decision upon receipt of the request. Reconsideration will take place at the next regularly scheduled Full Board meeting, in keeping with the application deadlines for submission.

4.2.3 The Researcher may attend the Full Board meeting in person and may be represented by a person of his or her choice; however, the Researcher and/or representative shall not be present during the HREB's deliberations.

4.3 Appeal of HREB Decisions

4.3.1 A Researcher may appeal a review decision or a reconsideration decision of the HREB or research ethics body by submitting a letter to the Chairperson of the HREA Appeal Panel. The Researcher will indicate any alleged breaches to the established research ethics review process, or any elements of the HREB decision that are not supported by TCPS2 or other relevant legislation, regulation or guidance. The Researcher may provide additional information for the Appeal Board's consideration. The Ethics Director will coordinate the Appeal process in consultation with the Chair of the Appeal Panel.

4.3.2 The Researcher may attend the Appeal Board meeting in person and may be represented by a person of his or her choice; however, the Researcher and/or representative shall not be present during the Appeal Board's deliberations.

4.3.3 The Appeal Board shall have the authority to review decisions made by the HREB. In so doing, it may uphold the appeal and substitute the decision it considers appropriate or may dismiss the appeal. Its decision shall be binding on the Researcher and the HREB and shall be communicated in writing with reasons for its decision.

4.3.4 A researcher may appeal the decision of the Appeal Board to Supreme Court Trial Division.

4.4 Documenting HREB Decisions

4.4.1 The HREB meetings minutes will satisfy the applicable requirements.

4.4.2 The HREB shall notify the Researcher in writing of its decision to approve, require changes to the application or refuse to approve the application.

4.4.3 The final approval letter will include standard conditions of approval to which the Researcher must adhere.

4.4.4 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 will be issued by the REO Personnel.

5.0 REFERENCES

Health Research Ethics Authority Act: An act to establish a health research ethics authority for the province. (2011). Retrieved from: SNL2006 CHAPTER H-1.2 - HEALTH RESEARCH ETHICS AUTHORITY ACT (assembly.nl.ca)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 6: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

Electronic Code of Federal Regulations, Title 45, Part 46: Electronic Code of Federal Regulations (eCFR)

6.0 VERSION HISTORY

Revision Date	Summary of Changes
April 2021	Original version
April 2024	4.1.3 Delegated review process