

TITLE	402: HREB Review Decisions
SCOPE	All research submitted to the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

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

2.0 RESPONSIBILITIES

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

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURE

As a result of its review, an HREB 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 HREB may defer its decision. When the Full Board review procedure is used, decisions will be made by consensus or a majority vote of the HREB members who are present at a Full Board meeting at which there is a quorum.¹

¹ See SOPs 302.3.3.1 and 201 for details regarding quorum and proper representation in HREB membership, respectively.

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 HREB and organization's conflict of interest policies.

When the delegated review procedure is used, the HREB Chair and/or HREB 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 HREB's decisions and to appeal the decision of the HREB.

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. The HREB Chair abstains from voting except to break a tie vote;
- 4.1.2 In the instance that there are Co-Chairs, one shall be designated at the start of the academic year to have tie-breaking powers. The other chair shall continue to vote as a committee member.
- 4.1.3 The HREB 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 local HREB procedure,
 - The expiry date of the HREB approval is calculated from this date.
 - Approval with Modifications/Clarifications:
 - 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 with Modifications/Clarifications",
 - When the HREB recommends "Approval with Modifications/Clarifications," the HREB Chair or designee should 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 should be delegated to one of the following:

- The HREB Chair alone,
 - The HREB Chair 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 Chair or designee or by the HREB,
 - A designated HREB member or members with sufficient knowledge and experience regarding the research and the regulations.
- In deciding the procedures to be followed, the HREB 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 HREB Chair or designee alone,
 - Where the additional information/modification is technical (e.g., statistical clarifications), the HREB Chair 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 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 local HREB procedures. The expiry date of the HREB 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 HREB 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 HREB 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 HREB 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 local HREB procedures. The expiry date of the HREB approval is calculated from this date; however, the approval letter is not issued until all the conditions for approval have been met.
- Disapproval:
 - The HREB may disapprove 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,
 - 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 HREB at a Full Board meeting,
 - The HREB 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.
 - If requested by the Researcher, the HREB must reconsider the disapproval at a Full Board meeting.
 - The Researcher is allowed to be present at the reconsideration meeting, but must leave the meeting when the decision is being made.
- 4.1.4 Delegated Reviews:
 - 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,

- When delegated review procedures are followed, approval is considered as the day the research is approved by the HREB Chair or designee as well as all other designated reviewer(s), if applicable. The expiry date of the HREB approval is calculated from this date; however, 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.

4.2 Reconsideration and Appeal of HREB Decisions

- 4.2.1 A Researcher may appeal the decision of the HREB if the disagreement between the Researcher/applicant and the HREB cannot be resolved through a reconsideration process at a Full Board meeting at which the Researcher/applicant shall have the right to be heard;
- 4.2.2 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 HREB prior to the initiation of an appeal process;
- 4.2.3 Appeals are conducted in accordance with the established organizational policy. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the Tri-Council Policy Statement. An appeal shall proceed only if the Vice Provost of Research and Graduate Studies agrees the appeal is not frivolous; or there was at least one dissenting member of the HREB. Appeals will take place at The King's University in Edmonton, as per our formal written agreement with that institution, where their HREB will act as our standing Appeal Board;
- 4.2.4 The appeal committee at The King's University shall have the authority to review negative decisions made by the HREB 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 HREB in writing.

4.3 Documenting HREB Decisions

- 4.3.1 The HREB meetings minutes will satisfy the applicable requirements;
- 4.3.2 The HREB shall notify the Researcher in writing of its decision to approve or disapprove the proposed research, or of modifications/clarifications required to secure approval of the research;
- 4.3.3 If the HREB defers its decision, the letter to the Researcher should include the issues of concern and what further information is required;
- 4.3.4 The final approval letter should include standard conditions of approval to which the Researcher must adhere;

4.3.5 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 HREB Office Personnel.

5.0 REFERENCES

See References.

6.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 402	November 14, 2019	Original version