

SOP Title	HSREB Review Decision
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

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

2. GENERAL POLICY STATEMENT

- 2.1. As a result of the review, the HSREB 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. HSREB members with a conflict of interest in the research under review may be present to answer any questions the Board may have with regards 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 HSREB Chair, Vice Chair(s), and/or HSREB member(s) who are assigned to review the research proposal can decide to approve the research or to request revisions to the research; the decision to disapprove/reject the research must be made by the Full Board;
- 2.4. Investigators have the right to request reconsideration of the HSREB's decisions and to appeal the decision.

3. RESPONSIBILITY

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

The HSREB Chair or Vice-Chair(s) is responsible for ensuring that a decision is made for every submission that is reviewed by the HSREB 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 HSREB 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 HSREB members on the online system. All HSREB members will receive an email notification prior to the HSREB meeting at which the study is scheduled to be reviewed;

5.1.2.1.3. Discussion of the research proposal at the HSREB 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 HSREB Chair, Vice Chair, or the application will be removed from the agenda and discussed at the next meeting.

5.2. HSREB Decision

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

5.2.2. The HSREB 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 as submitted

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, 2020, the date by which continuing review must occur is no later than Feb 1, 2021).

5.2.2.2. Approves research with Modifications/Clarifications

5.2.2.2.1. When an acceptable risk/benefit ratio exists, and the regulatory criteria required for approval are satisfied, but the REB members require modification to any aspect of the application or clarification or further information to secure approval, the REB may decide “Approval with Modifications/Clarifications”;

5.2.2.2.2. The HSREB 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 HSREB 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 HSREB Chair or Vice Chair alone;
 - ☐ The HSREB Chair or Vice Chair and one or more named HSREB members that were present at the meeting;
 - ☐ A sub-group of the REB members designated by the REB Chair or designee or by the REB;
 - ☐ A designated HSREB 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 HSREB 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 HSREB Chair or Vice Chair or designee 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, 2020, the date by which continuing review must occur is no later than Feb 1, 2021).

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

- 5.2.2.3.1. The HSREB 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 HSREB requires extensive revisions to any part of the research proposal;
- 5.2.2.3.2. The HSREB 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 HSREB shall be reviewed at a convened Full Board meeting;
- 5.2.2.3.4. Upon consideration of the research proposal along with the response from the Investigator, at the meeting, the HSREB should issue its final decision (approved, approved with modifications, deferral, or disapproved);
- 5.2.2.3.5. Investigator responses must be received and reviewed at a Full Board meeting. If the Investigator's response to the Recommendations issued by the HSREB 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 HSREB 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, 2020, the date by which continuing review must occur is no later than Feb 1, 2021).

5.2.2.4. Disapproval

- 5.2.2.4.1. The HSREB may disapprove a research proposal when it fails to meet the ethical standards for approval and where revisions are unlikely to enable the HSREB 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 HSREB Decisions

- 5.3.1. An Investigator may appeal the decision of the HSREB if the disagreement between the Investigator and Board cannot be resolved through a reconsideration process at a convened meeting of the HSREB 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 HSREB 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 HSREB 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 HSREB in writing.

5.4. Documenting HSREB Decisions

- 5.4.1. For each project, the responsible EO should ensure that the meeting minutes record the following:
- The decision made by the HSREB,
 - 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 HSREB 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 HSREB 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. The International Conference on Harmonization Good Clinical Practices, Sections 3;
- 6.3. US Food and Drug Administration (FDA) CFR Title 21 Part 50 and 56;
- 6.4. 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
403.001	Original	01/20/2014
403.002	Updated Erika Basile's position Administrative corrections for clarity Added sections 5.3 and 5.4	05/22/2014
403.003	Minor administrative changes for clarification	07/29/2014
403.004	Minor administrative changes for clarification	05/10/2016
403.005	Section 2.4 updated to clarify that only the Full Board has the authority to disapprove or reject a study	12/01/2017
403.006	Minor Administrative Changes	09/06/2018
403.007	Minor Administrative Changes	02/21/2020
403.008	Correction to previous change and minor administrative	09/30/2021
403.009	Administrative updates for clarification	01/27/2022
403.010	Administrative updates for clarification	01/29/2025