



## Research Ethics Board Standard Operating Procedures

### REB Review Determinations

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<b>ISSUED BY:</b>	Research Ethics Office		
<b>APPROVED BY</b>	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

#### 1.0 PURPOSE:

The purpose of this Standard Operating Procedure (SOP) is to describe the decisions that the Women's College Hospital (WCH) Research Ethics Board (REB) may make resulting from its review of proposed research.

As a result of its review, the WCH REB has the authority to approve, reject, or propose modifications to submitted research projects. If there are questions that must be addressed prior to a determination, the REB shall defer the action. When the full board review procedure is used, decisions will be made by consensus of REB members in attendance at a convened REB meeting with a quorum present. If consensus cannot be achieved, a vote will be taken.

REB members with a conflict of interest regarding the research will recuse themselves and may not be present during the discussion and decision.

When the delegated review procedure is used, the WCH REB Chair or delegate can make any of the determinations except to reject the research (*see WCH REB Delegated Review SOP*).

Investigators have the right to appeal the REB's decision.

#### 2.0 DEFINITION(S):

See Glossary of Terms

#### 3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB members, and Research Ethics Office (REO) staff.

The REB Chair, or designee, is responsible for ensuring that a decision is made on every submission reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly agreed to. The REB Chair is responsible for signing documents related to the REB review and approval of research. The REB Chair may delegate signing authority however the responsibility for oversight rests with the REB Chair. Delegation of signing authority must be in writing.

#### 4.0 PROCEDURES:

##### 4.1. REB Decisions



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The REB should reach one of the following decisions as a result of its review and deliberation of research submitted for initial or continuing review:

#### 4.1.1. Approval

- When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted.
- This decision is made by consensus of the REB members present, except for those who have recused themselves due to conflict of interest.
- If consensus cannot be achieved, a vote will be taken.
- At WCH, the approval date is defined as the date that the research was reviewed and approved at a convened REB meeting. The expiration date is calculated from this date.

#### 4.1.2. Propose Modifications

- When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, but the REB requires modifications to secure approval, the research may be approved pending modifications.
- This decision is made by consensus of the REB members present, except for those who have recused themselves due to conflict of interest.
- If consensus cannot be achieved a vote will be taken.
- The WCH REB Chair should ensure that the required modification(s) is specifically identified at the REB meeting.
- A review letter is written by the WCH Research Ethics Coordinator outlining the required modifications and/or explanations.
- The review letter is reviewed and signed by the WCH REB Chair or delegate and sent to the investigator for response.
- Once the investigator's response is deemed complete and satisfactory by the WCH REB Chair (with input from the reviewers as applicable), approval can be issued by the WCH REB Chair.
- When the investigator's revisions and/or responses are received by the REO, the reviewer(s) re-evaluate(s) the protocol on the basis of the adequacy of the changes made and/or responses provided. If there are remaining queries or concerns that have not be resolved, a second set of comments are provided to the investigator. If an outstanding query or concern cannot be resolved, the protocol shall be reviewed at the next convened REB meeting (see deferral to subsequent convened REB meeting).
- The approval date is defined as the date that the WCH REB Chair (or delegate) or full REB approves the investigator's responses. The expiration date is calculated from this date.

#### 4.1.3. Deferral to Subsequent Convened REB Meeting



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- The REB may defer its decision to a subsequent convened REB meeting when significant questions are raised during its review of the research. In this case, the research and the investigator's response materials shall be reviewed at a convened REB meeting.
- The WCH REB Chair may decide to invite the investigator and/or members of the research team to attend the REB meeting to respond to questions and provide clarification around the issues raised by the REB.
- Upon consideration of the complete response from the investigator at the meeting, the REB should issue its determination (approval, request for further modifications, deferral to subsequent convened REB meeting, or rejection).
- This decision is made by consensus of the REB members present, except for those who have recused due to conflict of interest.
- If consensus cannot be achieved, a vote will be taken.
- The approval date is defined as the date of the REB meeting that the decision to approve the study is confirmed. The expiration date is calculated from this date.

#### 4.1.4. Rejection/Not Approved

- The REB may reject a project when the research fails to meet the ethical or scientific standards at WCH for approval and where revision is unlikely to enable the REB to reach a positive determination.
- The decision is made by consensus of the REB members present, except for those who have recused themselves due to conflict of interest.
- If consensus cannot be achieved, a vote will be taken.
- Rejection of a study cannot be decided through the delegated review procedure.
- The WCH REB Chair should ensure that the reasons for rejection are identified at the REB meeting for communication to the investigator.
- If the research is not approved, the reasons for not approving the project will be communicated to the investigator and the investigator will be given an opportunity to respond in person or in writing.

#### 4.2. Delegated Reviews:

- 4.2.1. When research qualifies for delegated review and delegated review procedures are followed, approval is effective on the date that the WCH REB Chair or delegate confirms that the study is approved.
- 4.2.2. This process may involve the request, receipt, and review of additional information from the investigator.
- 4.2.3. The WCH REB Chair has the authority to approve, require modifications, or defer the decision to a convened REB meeting.
- 4.2.4. Rejection cannot be decided through the delegated review process.



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4.2.5. If the research is felt to be more than minimal risk or cannot be approved through the delegated review process it must be reviewed by the full board at a convened REB meeting.

#### 4.3. Documenting REB Decisions:

4.3.1. For each study, the WCH Research Ethics Coordinator ensures that the meeting minutes and/or attendance record includes the following:

- The REB's decision;
- If consensus is not achieved, the disputed matters and the outcome of a vote (i.e. the number of REB members in agreement, opposed, and abstained);
- REB members recused due to conflicts of interest;
- Any modifications required by the REB;
- Additional information requested from the investigator;
- The agreed procedures for considering that information.

4.3.2. The REB shall notify the investigator in writing of its decision to approve or reject the proposed research, or of modifications required to secure approval of the research.

4.3.3. If the REB defers its decision, the letter to the investigator should include the issues of concern, what further information is required, and notification that the information will be discussed at a subsequent convened REB meeting. The REB meeting schedule and deadlines for submission to the REB are available on the REB webpage.

4.3.4. The final approval letter should include standard conditions of approval to which the investigator must adhere and the period for which the REB approval is granted.

4.3.5. The WCH REB Chair is responsible for signing documents related to the REB review and approval of research. The WCH REB Chair may delegate signing authority; however, the responsibility for oversight rests with the WCH REB Chair. Delegation of signing authority must be in writing.

4.3.6. Investigators have the right to appeal the REB decisions (see REB-SOP-IV-10.001 – Appeals).

#### 5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Chapters 1, 2, 6
2. The International Conference on Harmonization Good Clinical Practices (GCP Guidelines as adopted by Health Canada, Section 3.0
3. US Department of Health and Human Services (HHS) Title 45 CFR 46.109, 46.111
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 50 and 56
5. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Research Ethics Board Review Determinations* (REB-SOP-IV-01.003)