IWK Health

IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.402**	Title: **Review of Decision Determinants**	Effective Date: **November 19, 2024**
Pages**: 4**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

Following review, the REB may approve, reject, require modification to, or defer the decision on an application for ethical approval of a specific tabled project. Decisions of the Board will be by consensus or recorded majority vote.

When the delegated review procedure is used, the REB Chair or designee can make any of the determinations except to reject the research (see Delegated Review Process REB SOP 4.403).

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

REB Decisions

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. Available decisions are:

1. Approval
    a. Where an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted
    b. This decision is made by a consensus of the members present, except for those who have recused themselves due to conflict of interest; if consensus cannot be achieved, a vote will be taken
    c. The approval date is defined as the date of the letter confirming that the research was reviewed and approved at a convened REB meeting. The expiration date is

calculated from the date of approval

2. Approval with Modifications
    a. This qualified approval may be offered where, although an acceptable risk/benefit ratio exists and any regulatory criteria required for approval are satisfied, the Board nonetheless requires some additional modifications to meet institutional standards
    b. This decision is made by a consensus of the members present, except for those who have recused themselves due to conflict of interest; if consensus cannot be achieved, a vote will be taken
    c. The REB Chair should ensure that the required modification(s) is specifically identified at the meeting
    d. The Chair or Manager will write a comment letter outlining the required modifications and or explanations
    e. The comment letter will be reviewed by the Chair or delegate and sent to the Investigator for response
    f. If the Investigator's response is deemed complete and satisfactory the Chair may (with input from the reviewers as necessary or applicable) grant full approval, in which case an Approval Letter will be issued accordingly
    g. If the Investigator's response is incomplete and does not fully address the matter raised, the matter will be returned to the Investigator with requests for further information or clarification

3. Deferral to Subsequent Convened REB meeting
    a. The Board may defer its decision to a subsequent convened meeting when significant questions are raised during its review of the research
    b. In this case, the research and the investigator's response materials shall be reviewed at a convened REB meeting
    c. The Chair may invite the Investigator to attend the Board meeting to respond to questions and provide clarification around the issues raised by the members
    d. After due consideration of the complete response from the investigator at the meeting, the Board will determine if the project should be approved, approved with further modification, deferred pending further information, or rejected
    e. This decision is made by a consensus of the members present, except for those who have recused due to conflict of interest; if consensus cannot be achieved, a vote will be taken

4. Rejection/Not Approved
    a. The Board may reject a project when the research fails to meet its ethical or scientific standards for approval and where revision is unlikely to enable the Board to reach a positive determination
    b. This decision is made by a consensus of the members present, except for those who have recused themselves due to conflict of interest; if consensus cannot be achieved, a vote will be taken
    c. The Chair should ensure that the reasons for rejection are identified and recorded at

the meeting. The reasons for rejection will be communicated to the Investigator in writing and the investigator will be given opportunity to respond in person or in writing.

Decisions for Delegated Reviews

When the research qualifies for delegated review and the prescribed delegated review procedures (as outlined in TCPS2 Article 6.12 and detailed in REB SOP 4.403) have been followed and the project deemed acceptable, the Chair will write a letter of approval to the Investigator. Such approval is effective on the date of the letter of confirmation.

- This process may involve the request, receipt and review of additional information from the investigator
- The Chair has the authority to approve, require modifications, or defer the decision to a convened meeting
- Rejection cannot be decided through the delegated review procedure; if the research is felt to be more than minimal risk or cannot be approved through the delegated review procedure, it must be reviewed by the full Board at a convened meeting

Documenting REB Decisions

For each study, REB decisions will be recorded in the minutes as defined in REB SOP 3.301 (REB Meeting Administration).

Additional Considerations

Clinical trials that require a regulatory submission (either initial or at time of amendment) may be granted provisional approval to allow for submission to Health Canada, but final REB approval (and hence permission to start the research) will only be granted on receipt of a formal 'No Objection' letter from Health Canada.

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Chapter 1, 2, 6;
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada, Section 3.0;
3. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 50 and 56; 4. US Department of Health and Human Services (HHS) Title 45 CFR 46.109, 46.111.

Forms/Records:

Form #	Form/Record Name
SOP 402	Review Decision Determinants

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Removed unclear wording, added note regarding compliance with US regulations where applicable