TITLE	**106: HREB Signatory Authority**
SCOPE	The activities of the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	July 21, 2022

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe who has the authority to sign documents on behalf of the HREB and describes the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All 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 signing documents related to HREB review and approval of health research. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the HREB Chairperson.

4.0 PROCEDURE

The HREB is accountable for their activities and decisions, and appropriate controls must be applied to ensure that documentation related to HREB review and approval of research are signed by a person or persons having the appropriate authority to do so.

4.1 Delegation of Signing Authority

4.1.1 The HREB Chairperson may delegate signing authority for documents related to HREB review and approval.

4.1.2 The HREB Chairperson may not delegate his/her signing authority to ad hoc advisors or to independent contractors.

4.1.3 The HREB Chairperson will clearly define the parameters of the delegated signing authority.

4.1.4 The HREB Chairperson may delegate signing authority indefinitely or for defined periods of time (e.g., for absences).

4.1.5 Delegation of signing authority will be documented and kept on file.

4.2 Results of HREB Reviews, Decisions and Other Correspondence with the Researcher

4.2.1 HREB decisions made at a Full Board meeting will be recorded in the meeting minutes and approved by the HREB Chairperson. The decisions will be reported to the researchers as documented in the meeting minutes. Decisions made on new applications, as well as amendments that are reviewed at a Full Board meeting, will be communicated in a letter to the Researcher.

4.2.2 For each submission that undergoes delegated review, the reviewer's decision will be documented in the Researcher Portal.

4.2.3 Once a final decision is documented by the HREB Chairperson or designee, the responsible REO Personnel will issue the decision or letter.

4.2.4 All reviews, actions, decisions, formal correspondence and signatures will be filed within the research file.

5.0 REFERENCES

International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), Section 3: ICH GCP - 3. INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC) - ICH GCP

6.0 VERSION HISTORY

Revision Date	Summary of Changes
April 2021	Original version
July 21, 2022	4.2.1 Clarified which decisions communicated by letter