fraserhealth	**RESEARCH ETHICS BOARD** **STANDARD OPERATING PROCEDURES**	
	SOP Number	106
	Signatory Authority	
	Date of Issue **Date of Revision**	2010 05 12 2018 03 30 2022 07 13

Purpose: This standard operating procedure (SOP) specifies who has the authority to sign documents on behalf of the Research Ethics Board (REB) and describes the responsibilities of such individuals, and the circumstances under which signing authority may be delegated.

References: 2019 10 08 CAREB SOP 106.003, Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, Article 6.17, The International Conference on Harmonization Guidelines for Good Clinical Practice E6(R2), Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 115, US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.108, 56.115.

Responsibility: All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

The REB Chair or designee is responsible for signing documents related to REB review and approval of research. If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair.

Procedure

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

1.0 Delegation of Signing Authority

1.1 The REB Chair or designee may delegate signing authority for documents related to REB review and approval;

1.2 The REB Chair or designee may only delegate signing authority to REB members or to the REB Office Personnel with the skill and knowledge necessary for the effective exercise of the authority;

1.3 The REB Chair or designee may not delegate their signing authority to ad hoc advisors or to independent contractors;

1.4 The REB Chair or designee should clearly define the parameters of the delegated authority;

1.5 The REB Chair or designee may delegate signing authority indefinitely or for defined periods of time (e.g., for absences);

1.6 Delegation of signing authority shall be documented and kept on file.

2.0 REB Reviews, Decisions and Other Correspondence with the Research

2.1 For each submission reviewed at a Full Board meeting, the responsible REB Office Personnel records the decision made by the Full Board;

2.2 Communication of the REB decision made at a Full Board meeting must be reviewed and authorized by the REB Chair or designee or as otherwise delegated by the REB Chair or designee;

2.3 For each submission that undergoes delegated review, the reviewer's decision is documented;

2.4 Once a final decision is documented by the REB Chair or designee, the responsible REB Office Personnel may issue the decision or letter;

2.5 All activities are documented in the research file;

2.6 Any letters, memos, or emails between the REB and Researchers that provide information concerning the review of research (e.g., requests for consent form changes, requests for additional information) and that do not imply or appear to imply approval of the research, may be issued as per delegated signing authority;

2.7 All correspondence is retained in the research file.

3.0 Correspondence with External Agencies

3.1 The responsible Organizational Official or the REB Chair or designee signs all correspondence with agencies of the federal government (Health Canada, OHRP, FDA) and with all funding agencies and/or sponsors.