SOP 106.004

Title	**Signatory Authority**
SOP Code	106.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	**Signature**	**Date** MM/DD/YYYY
Meera Sidhu, Research Ethics Manager	M Sidhu	12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023

1.0 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.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

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 the 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.

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REB Office Personnel are currently delegated to perform the following tasks on behalf of the REB:

- **Acknowledgement/Approval of Minor Administrative Changes**
- **Administrative Review of Initial Applications and Event Forms**
- **Acknowledgement/Approval of Team Member Changes (not for PI changes)**
- **Acknowledgement/Approval of Study Closures**
- **Acknowledgment of Protocol Deviation/Adverse Events**
- **Approval of Renewals with no changes/increase in risk**
- **Approval of Case Report Forms**
- **Approval of Non-Recruitment/Secondary Data Use Protocols**
- **Preliminary Reviews of LOI/CFs**
- **Preliminary Reviews for New Applications Requiring Full Board Review**
- **Preliminary Reviews for Amendments Requiring Full Board Review**
- **Preliminary Reviews for New Applications Requiring Delegated Review**
- **Preliminary Reviews for Amendments Requiring Delegated Review**
- **Preliminary Principal Investigator (PI) Responses to Delegated Reviews**
- **Preliminary Reviews for PI Responses to Full Board Reviews**
- **Preliminary Reviews for Protocol Deviations/Adverse Events/Serious Adverse Events**

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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

5.1 Delegation of Signing Authority

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

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

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

5.1.4 The REB Chair or designee should clearly define the parameters of the delegated authority.

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

5.1.6 Delegation of signing authority must be documented and kept on file **(electronic or hardcopy).**

5.2 REB Reviews, Decisions and Other Correspondence with the Researcher

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

5.2.2 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.

5.2.3 For each submission that undergoes delegated review, the reviewer's decision is documented.

5.2.4 Once the REB Chair or designee documents a final decision, the responsible REB Office Personnel may issue the decision or letter.

5.2.5 All activities are documented in the research file.

5.2.6 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.

5.2.7 All reviews, actions, decisions and signatures are filed within the research file.

5.2.8 All correspondence is retained in the research file.

5.3 Correspondence with External Agencies

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

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP106.001	15-Sept-2014	Original version
SOP106.002	08-Mar-2016	No revisions needed
SOP106.003	08-Oct-2019	No revisions needed
SOP106.004	15-May-2023	No revisions needed
SOP106.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text