RESEARCH ETHICS BOARDS - SIGNATORY AUTHORITIES 520

Procedures are a series of required steps to complete a task, activity or action

Purpose:	To provide a standardized approach to describe who has the authority to sign documents on behalf of the Research Ethics Boards (REBs) and describe the responsibilities of such individuals, and circumstances under which signing authority may be delegated.

Scope:	• Affected Roles
	  • REB Office Personnel
	  • REB Chairs and members
	• Environment
	  • Research Environment

Outcomes:	• REB Chairs, members and REB Office Personnel will understand who signs REB related documents and when in different circumstances.

1 RESPONSIBILITY

All REB Chairs, members, and REB Office Personnel are responsible for ensuring that the requirements of this Standard Operating Procedure (SOP) are met.

2 PROCEDURE

The REB Chair(s) or designate is authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as participants. These research projects have been reviewed and approved according to REB policies and procedures, and upon decision of the REB. Implementation of this procedure shall be the responsibility of the REB Chairs and Manager, as well as the REB Coordinators.

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 are signed by a person or persons having the appropriate authority to do so.

2.1 Authorization and Delegation of Signing Authority

- Authorization to sign documents related to REB activities not described in this policy may be made by the REB Chairs.
- The REB Chair(s) or designate may delegate signing authority for documents related to REB review and approval.
- The REB Chair(s) or designate may only delegate signing authority to REB members or REB Office Personnel with the skill and knowledge necessary for effective exercise of the authority.
- The REB Chair(s) or designate may not delegate their signing authority to ad hoc advisors or to independent contractors.
- The REB Chair(s) or designate should clearly define the parameters of the delegated authority.
- The REB Chair(s) or designate may delegate signing authority indefinitely or for defined periods of time (e.g. absences).
- Delegation of signing authority must be documented and kept on file.

2.2 Results of REB Reviews, Decisions, and Other Correspondence with the Researcher

- For each submission reviewed at a Full Board meeting, the responsible REB Office Personnel records the decision made by the Full Board.
- The results of reviews and actions taken by the REB, either by the full Board, subcommittee, or delegated review, that grant Researchers initial or continuing approval of research projects involving human participants may be signed by the REB Chair(s) or their designate, or as otherwise delegated by the REB Chair(s) or designate.
- For each submission that undergoes delegated review, the reviewer's decision is documented in the applicable online database.
- The REB's approval or rejection of an application for study approval must be communicated to the Principal Investigator (PI)/Qualified Investigator (QI) by written formal correspondence from the REB via the applicable online database. Once a final decision is documented by the REB Chair(s) or designate, the responsible REB Office Personnel may issue the decision or letter.
- Certificates of approval are electronically issued by REB Office Personnel, subsequent to approval being noted by the REB Chair(s) or designate within the Correspondence section of the applicable online database.
- The applicable online database records the REB Chair(s) or designate's written decision regarding approval or rejection. This, and the security provided by the login user ID and password, are an electronic signature;
- All activities are documented in the applicable online database.
- 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.
- All reviews, actions, decisions and signatures are filed within the research file.
- Correspondence and communication between the REB and the PI/QI is coordinated through REB Office Personnel. Decision-point correspondence is logged and retained under the applicable study number within the applicable online database.
- REB approval of renewals, amendments and other forms of continuing review will be issued by REB Office Personnel through the applicable online database when the required approval from the Chair(s) or designate is received. This communication will be found in the study related correspondence within the applicable online database.

3 CORRESPONDENCE PROVIDING APPROVAL OF POST-APPROVAL ACTIVITIES

3.1 REB approval of amendments and continuing review will be issued by REB Office Personnel upon the requisite approval having been granted and documented by the Chair(s) or designate.

4 CORRESPONDENCE WITH EXTERNAL AGENCIES

4.1 The responsible Organizational Official or the REB Chair(s) or designee signs all correspondence with agencies of the Federal Government (Health Canada, Office for Human Research Protections, Federal Drug Administration) and with all funding agencies and/or sponsors as such correspondence relates to the activities of the REB.

5 TRAINING

5.1 Review of the SOP

6 COMPLIANCE MONITORING

6.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify compliance with this SOP.

6.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for communicating any changes to this SOP to all relevant personnel.

7 DEFINITIONS

- See Glossary of Terms– Research Ethics

8 REFERENCES

- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 5.3: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter5-chapitre5.html#3

9 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	01 JUL 2013	New procedure
2.0	09 AUG 2021	Reflection of current process; Removed 'mail' as a correspondence option; Removed conflict of interest(COI) for signing authority – moved to new 528 SOP Conflicts of Interest REB Members and REB Office Personnel; Minutes moved to SOP 506 REB Meeting Administration