

SOP 106.001

Title	Signatory Authority
SOP Code	106.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy

1.0 PURPOSE

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

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies 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 authorizing documents and decisions related to REB review and approval of research. If authority is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair.

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 are authorized by a person or persons having the appropriate authority to do so. Documentation includes both hard copy and electronic formats. Signing may be done with ink, e-signature or scanned signature, as per REB/organizational policies and procedures.

5.1 Delegation of Signing Authority

- 5.1.1 The REB Chair or designee may delegate signatory 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 his/her signing authority to ad hoc advisors or to 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 of time (e.g., for absences);
- 5.1.6 Delegation of signing authority must be documented and retained.

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;

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- 5.2.4 Once a final decision is documented by the REB Chair or designee, the responsible REB Office Personnel may issue the decision or letter;
- 5.2.5 All activities are documented in the research file, which may be physical or electronic;
- 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), may be issued as per delegated signing authority;
- 5.2.7 All reviews, actions, decisions and signatures (where applicable) 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 all governmental or funding agencies and/or sponsors.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP106.001		Original version