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| **Title** | Signatory Authority |
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| **N2/CAREB SOP CODE** | SOP 106-003 |
| **Effective Date** | YYYY-MM-DD |

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# 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.

# Scope

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

# Responsibilities

All REB members and designated REB staff 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.[[1]](#footnote-1) If the task of signing is delegated to a qualified individual or individuals, the responsibility for oversight remains with the REB Chair.

# Definitions

See Glossary of Terms.

# Procedures

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.

## Delegation of Signing Authority

### The REB Chair or Vice-Chair, as part of their duties, have the authority to act as signing officers for the duration of their term;

### The REB Chair or Vice-Chair may delegate signing authority for documents related to REB review and approval;

### The REB Chair or Vice-Chair may only delegate signing authority to REB members or REB Support Staff with the skill and knowledge necessary for the effective exercise of the authority;

### The REB Chair or Vice-Chair should clearly define the parameters of the delegated authority, including the scope of the signing authority and the duration of the delegation of signing authority;

### Delegation of signing authority to other REB members or Support Staff must be documented and kept on file.

## REB Reviews, Decisions and Other Correspondence with the Researcher

### For each submission reviewed at a Full Board meeting, the responsible REB Support Staff records the decision made by the Full Board;

### Communication of the REB decision made at a Full Board meeting or at a delegated review must be reviewed and authorized by the REB Chair or Vice-Chair or as otherwise delegated by the REB Chair or Vice-Chair;

### For each submission that undergoes delegated review, the reviewer’s decision is documented;

### Once a final decision is documented by the REB Chair or Vice-Chair, the responsible REB Support Staff may issue the decision in writing[[2]](#footnote-2) or send a letter;

### All activities are documented in the research file;

### 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;

### All correspondence is retained in the research file.

## Correspondence with External Agencies

### 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.

# References

See footnotes.

# Revision History

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| --- | --- | --- |
| **SOP Code** | **Effective Date** | **Summary of Changes** |
| REB-SOP 106-001 | 2019-04-01 | Original version |
| REB-SOP 106-002 | YYYY-MM-DD | Updated in line with regulations in effect Updated references |
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# Appendices

1. Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, s. 8.14. [↑](#footnote-ref-1)
2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018, Application under art. 6.8. [↑](#footnote-ref-2)