

Title	Duties of REB Members
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1 PURPOSE

This standard operating procedure (SOP) describes the duties of the members of the Research Ethics Board (REB).

2 SCOPE

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

3 RESPONSIBILITIES

All REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met.

REB members are responsible for fulfilling their duties as specified in this SOP.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

Each REB member will ensure that any research submitted for their review safeguards the dignity, rights, safety, and well-being of human participants in a research study.¹ Each REB member will also ensure the promotion of quality research. In order to fulfill his or her duties, each REB member must be versed in regulations governing biomedical research ethics and the protection of human participants as well as in policies germane to human research participant protection.²

5.1 Attendance

5.1.1 REB members are expected to attend REB meetings to which they are convened;

5.1.2 REB members must notify the REB office if they will be absent for an REB meeting to which they are convened, in order to ensure that quorum can still be met and/or so that an appropriate alternate may attend in his/her place.

5.2 Duties

5.2.1 All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB in advance, and to be prepared to discuss

¹ ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter “ICH GCP”, s. 3.1.1.1; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter “Modèle”, s. 4.1; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter “TDR”, s. 2.

² Mainly, but not only, the 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 2014 (TCPS2).

them at the meeting. In so doing, they will pay particular attention to elements involving the areas of expertise expected of their mandate and for which they were called to serve on the REB;

- 5.2.2 All REB members participating in a delegated ethics review are expected to review the relevant materials submitted for each item under review or consideration by the REB, and to submit their comments or be prepared to discuss them within the timeframe specified by the REB;
- 5.2.3 REB members appointed for their expertise in scientific matters, ethics, or law will pay particular attention to elements involving the areas of expertise expected of their mandate and for which they were called to serve on the REB³;
- 5.2.4 Community members are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective. They are essential to help broaden the perspective and value base of the institution, and thus advance dialogue with, and accountability to, local groups.⁴

5.3 REB Chair

- 5.3.1 The REB Chair provides overall leadership to the REB and facilitates the REB review process based on the institution's policies and procedures.⁵ This includes the following:
- The REB Chair can delegate any of his/her responsibilities, as appropriate, to a Vice-Chair or other qualified individual(s),
 - Any responsibilities that are delegated by the REB Chair must be documented,
 - The REB Chair or designee facilitates the review process based on organizational policies and procedures, SOPs, and applicable regulations and guidelines,
 - The REB Chair or designee monitors the REB's decisions for consistency,
 - The REB Chair or designee ensures that all REB members are free to participate in discussions during REB meetings,
 - The REB Chair or designee can ask an ad hoc advisor to attend an REB meeting in order to draw his/her expertise in an area that may be relevant to the REB's review and deliberations of the research,
 - The REB Chair or designee determines whether the research is appropriate for delegated review,
 - The REB Chair or designee ensures that REB decisions are accurately input into the minutes and clearly communicated to researchers in writing,
 - For REB approval of clinical trials approved by Health Canada, the REB approval letter and REB attestation, if not already included in the approval letter, is signed by the REB Chair or designee,

³ *Modèle*, s. 6.7.2; TCPS2, ch. 6.

⁴ *Modèle*, s. 6.7.2; TCPS2, p. 74.

⁵ TCPS2, art. 6.8.

- The REB Chair or designee can suspend the conduct of any research project if he/she deems that a change has rendered it unacceptable to:
 - place participants at a new unacceptable risk level, and
 - wait for the next REB Full Board Meeting to discuss it.

The change in risk may be related to circumstances including, but not limited to, a Researcher not adhering to the REB approved protocol or to the REB's policies and procedures,

- The REB Chair or designee will report on the activities of the REB to the Board of Directors on an annual basis,
- The REB Chair, in conjunction with the REB Support Staff, shall assess the educational and training needs of REB members and Support Staff,
- The REB Chair or designee reviews REB policies and procedures as needed, to ensure that REB SOPs meet all current standards.

5.4 REB Vice-Chair

- 5.4.1 In addition to performing responsibilities delegated by the REB Chair, the REB Vice-Chair or equivalent is responsible for performing the responsibilities of the REB Chair when the REB Chair is unable to do so.

5.5 Training and Education

- 5.5.1 REB members are expected to follow training and education procedures.⁶

5.6 Conflict of Interest

- 5.6.1 REB members are expected to follow conflict of interest procedures.⁷

6 REFERENCES

See footnotes.

⁶ See REB SOP 103.001.

⁷ See REB SOP 105A.001.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 203.001	2020-03-20	Original version (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)

8 APPENDICES