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| **Title** | Authority and Purpose |
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# Purpose

The purpose of this standard operating procedure (SOP) is to:

* State the organizational authority under which the Research Ethics Board (REB) is established and empowered;
* Define the purpose of the REB;
* State the principles governing the REB to assure that the rights and welfare of participants are protected;
* State the authority of the REB.

# Scope

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

# Responsibilities

The Board of Directors, all REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met.

# Definitions

See Glossary of Terms.

# Procedures

The REB will maintain and follow all written policies and procedures consistent with federal and provincial regulations, good clinical practice, and ethics guidelines when reviewing proposed research.

## Statement of Organizational Authority

### The Board of Directors of the institution has established and empowered the REB to review research involving human participants conducted under the auspices of the institution. The REB is directly attached to the Board of Directors.[[1]](#footnote-2)

### All research involving human participants is to be reviewed and approved by an REB prior to the initiation of any research-related activities.[[2]](#footnote-3)

## Purpose of the REB

### The REB’s purpose is to protect the dignity, rights, and welfare of human participants in research[[3]](#footnote-4);

### The REB’s purpose is also to sensitize the various stakeholders to ethical principles applicable to research involving human beings;

### The REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection[[4]](#footnote-5);

### These include, but are not limited to: the Quebec *Cadre de référence ministériel pour la recherche avec des participants humains*; the Framework for Public Health and Social Services Institutions to Authorize Research Conducted at More Than One Institution; the Civil Code of Québec; the Quebec Act Respecting Health Services and Social Services; the Quebec Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information; the Quebec Act Respecting the Protection of Personal Information in the Private Sector; Canada’s Food and Drugs Act and Regulations; Good Clinical Practice: Integrated Addendum to E6(R1) ICH Topic E6(R2), Health Canada; the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; the UNESCO Universal Declaration on Bioethics and Human Rights; the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), 2018; the Canadian General Standards Board Research Ethics Oversight of Biomedical Clinical Trials (CAN/CGSB-191.1-2013); and where applicable, US Federal Regulations.

## Governing Principles

### The REB is guided by the ethical principles[[5]](#footnote-6) regarding all research involving human participants, including:

* Respect for Persons:

1. Recognize the intrinsic value of human beings and the respect and consideration they are due,
2. Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy;

* Concern for Welfare:

1. Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
2. Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
3. Ensure that participants are not exposed to unnecessary risks;

* Justice:

1. Obligation to treat people fairly with equal respect and concern,
2. Vulnerable or marginalized people may need to be afforded special attention.

## REB Authority

### The REB has the authority to review, in an independent manner and without any undue influence,[[6]](#footnote-7) all research involving human participants within its established jurisdiction[[7]](#footnote-8);

### The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants;

### Specifically, the REB has the authority[[8]](#footnote-9) to:

* Establish the research ethics review and oversight processes to ensure the ethical conduct of research projects,
* Approve, require modifications to, or not approve, any research activity that falls within its jurisdiction,
* With active follow-up, ensure that the researcher follows policies and procedures to protect the rights, safety and welfare of research participants,
* Request, receive and share any information involving the research that the REB considers necessary to fulfill its mandate, while maintaining confidentiality and respecting privacy,
* Conduct continuing ethical review to protect the rights and welfare and privacy of research participants,
* Suspend or terminate the ethics approval for the research,
* Place restrictions on the research,
* Take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB’s jurisdiction.

## Research Subject to Foreign Regulations

The REB shall respect the requirements of the applicable foreign regulations, if applicable.

# References

See references.

# Revision History

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| **SOP Code** | **Effective Date** | **Summary of Changes** |
| REB-SOP 101-001 | 2019-04-01 | Original version |
| REB-SOP 101-002 | YYYY-MM-DD | Updated in line with regulations in effect Updated references |
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# Appendices

1. 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, hereafter “TCPS2”, art. 6.1 and 6.2. [↑](#footnote-ref-2)
2. REB-SOP 102-002, s. 5.1. [↑](#footnote-ref-3)
3. Guidance Document: Good Clinical Practice: Integrated Addendum to E6(R1) ICH Topic E6(R2), Health Canada, April 2019, hereafter “ICH GCP”, s. 3.1.1; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter “TDR”, s. 2. [↑](#footnote-ref-4)
4. *Cadre de référence ministériel pour la recherche avec des participants humains, Gouvernement du Québec, Ministère de la Santé et des Services sociaux*, October 2020, hereafter “*Cadre*”, art. 3.1. [↑](#footnote-ref-5)
5. TCPS2*,* art. 1.1; TDR, s. 2. [↑](#footnote-ref-6)
6. TDR, s. 2; *Cadre*, art. 2.4.4; TCPS2, art. 6.2. [↑](#footnote-ref-7)
7. REB-SOP 101, s. 5.1.1 (territorial jurisdiction); REB-SOP 102, s. 5.1.1 (subject-matter jurisdiction) and TCPS2, art. 2.1 to 2.6 (subject-matter jurisdiction). [↑](#footnote-ref-8)
8. *Cadre*, art. 2.5.4; ICH GCP, s. 3.1; TCPS2, art. 6.3. [↑](#footnote-ref-9)