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**1 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.

## 2 SCOPE

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

## 3 RESPONSIBILITIES

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

## 4 DEFINITIONS

See Glossary of Terms.

## 5 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.

### 5.1 Statement of Organizational Authority

- 5.1.1 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<sup>1</sup>;
- 5.1.2 All research involving human participants is to be reviewed and approved by an REB prior to the initiation of any research-related activities.

### 5.2 Purpose of the REB

- 5.2.1 The REB's purpose is to protect the dignity, rights, and welfare of human participants in research<sup>2</sup>;

<sup>1</sup> 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, hereafter "TCPS 2", art. 6.2.

<sup>2</sup> ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.1.1; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Ministère de la Santé et des

- 5.2.2 The REB's purpose is also to sensitize the various stakeholders to ethical principles applicable to research involving human beings<sup>3</sup>;
- 5.2.3 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<sup>4</sup>;
- 5.2.4 These include, but are not limited to, the Quebec *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (PAM), the *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, 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; Canada's Food and Drugs Act and Regulations; the International Conference on Harmonisation Good Clinical Practice Guidelines; the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2); the Canadian General Standards Board Research Ethics Oversight of Biomedical Clinical Trials (CAN/CGSB-191.1-2013); and where applicable, US Federal Regulations.

### 5.3 Governing Principles

- 5.3.1 The REB is guided by the ethical principles<sup>5</sup> regarding all research involving human participants, including:
- Respect for Persons:
    - Recognize the intrinsic value of human beings and the respect and consideration they are due,
    - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy;
  - Concern for Welfare:
    - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
    - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
    - Ensure that participants are not exposed to unnecessary risks;

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*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.

<sup>3</sup> *Modèle*, s. 4.1; *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique*, Gouvernement du Québec, Ministère de la Santé et des Services sociaux, June 1998, hereafter "PAM", p. 13.

<sup>4</sup> PAM, p. 13.

<sup>5</sup> TCPS2, art. 1.1; TDR, s. 2.

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

## 5.4 REB Authority

5.4.1 The REB has the authority to review, in an independent manner,<sup>6</sup> all research involving human participants within its established jurisdiction<sup>7</sup>;

5.4.2 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;

5.4.3 Specifically, the REB has the authority<sup>8</sup> to:

- Establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,
- Approve, require modifications to, or disapprove, 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.

## 5.5 Research Subject to Foreign Regulations

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

## 6 REFERENCES

See references.

<sup>6</sup> TDR, s. 2; *Modèle*, s. 5.1; TCPS2, p. 70 and 71.

<sup>7</sup> TCPS2, art. 2.1 to 2.6.

<sup>8</sup> *Modèle*, s. 4; PAM, p. 13-14; ICH GCP, s. 3.1; TCPS2, art. 6.3.

## 7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 101.001	2020-03-20	Original version (MUHC Board of Directors acknowledged 2020-03-20; approved 2021-03-22)

## 8 APPENDICES