

<b>Title</b>	<b>Authority and Purpose</b>
<b>SOP Code</b>	101.001
<b>Effective Date</b>	2022-NOV-04

**Site Approvals**

<b>Name and Title</b>	<b>Signature</b>	<b>Date (yyyy.mm.dd)</b>
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**1.0 PURPOSE**

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

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

**2.0 SCOPE**

This SOP pertains to the Human Research Ethics Board (HREB), Mount Royal University.

**3.0 RESPONSIBILITIES**

Mount Royal University Organizational Officials (the “Organization”), all HREB members and HREB Office Personnel are responsible for ensuring that the

requirements of this SOP are met.

## **4.0 DEFINITIONS**

See Glossary of Terms

## **5.0 PROCEDURE**

HREB receives its mandate from the highest level of the Organization and will fulfill this mandate by following all relevant ethical policies, standards, procedures and legal and regulatory requirements.

### **5.1 Statement of Organizational Authority**

5.1.1 HREB is established and empowered under the authority of the organization to review ethical acceptability of all research involving human participants conducted under the auspices of the Organization (as per SOP 102);

5.1.2 The Organization requires that all research involving human participants be reviewed and approved by HREB prior to initiation of any research related activities.

### **5.2 Purpose of the REB**

5.2.1 HREB's purpose is to protect the rights and welfare of human research participants;

5.2.2 HREB reviews and oversees the research to ensure that it meets ethical standards and that it complies with all applicable requirements pertaining to human research participant protection;

5.2.3 These include, but are not limited to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and where applicable, the US Federal Policy for the Protection of Human Subjects (Final Common Rule).

### **5.3 Governing Principles**

5.3.1 HREB is guided by ethical principles 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.
  
- 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 HREB is established to review all research involving human participants within its established jurisdiction;

5.4.2 HREB 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, HREB has the authority 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,
- 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 HREB considers necessary to fulfil its mandate, while maintaining

- confidentiality and respecting privacy,
- conduct ongoing and continuing ethics review to protect the rights and welfare of research participants,
- suspend or terminate 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 HREB's jurisdiction

### **5.5 Research Subject to US and International Regulations**

HREB shall apply the requirements of the applicable US and International regulations to the extent that they vary from the protections set out in the applicable Canadian policies and guidelines, where required.

## **6.0 REFERENCES**

See References.

## **7.0 REVISION HISTORY**

<b>SOP Code</b>	<b>Effective Date</b>	<b>Summary of Changes</b>
SOP 101.001	2022.11.04	Original version