Research Ethics Board

Standard Operating Procedure

SOP File #	**REB.SOP.101**
Title	Authority and Purpose
Effective Date	July 1, 2021
Next Review	2026
Next Administrative Review	2023

1. Purpose

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

1.1. State the organizational authority under which the Research Ethics Board (REB) is established and empowered;

1.2. Define the purpose of the REB;

1.3. State the principles governing the REB to assure that the rights and welfare of participants are protected;

1.4. State the authority of the REB.

2. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. Scope

This SOP pertains to the University REB(s) at Mount Saint Vincent University (MSVU) that review human participant research in compliance with applicable policies and guidelines.

4. Responsibilities

The responsible MSVU Official(s), all REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

5. Procedures and/or Specific Policies

The REB receives its mandate from the highest level of authority at MSVU (also see REB.POL.002 – REB Terms of Reference) and will follow all written policies and procedures consistent with federal and provincial regulations, relevant ethical policies (e.g. Policy: The Interagency Advisory Panel on Research Ethics (PRE), Good Clinical Practice), standards, procedures, and legal and regulatory requirements.

5.1. Statement of Organizational Authority

5.1.1. The REB is established and empowered under the authority of MSVU to review ethical acceptability of all research involving human participants conducted under the auspices of MSVU (as per REB.SOP.102);

5.1.2. MSVU, under the direction of the Provincial and Federal Governments, requires that all research involving human participants be reviewed and approved by the REB **prior** to initiation of any research related activities.

5.2. **Purpose of the REB**

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

5.2.2. The REB 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;

- 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).
- Research that falls under Medical or Clinical research shall also meet regulatory requirements including, but not limited to, the Food and Drugs Act and applicable Regulations, the International Council on Harmonization, Good Clinical Practice Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, and where applicable, US Federal Regulations.

5.3. **Governing Principles**

The REB 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. The REB is established to review all research involving human participants within its established jurisdiction;

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.

Specifically, the REB 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 includes human participants,
- 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 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 research involving human participants,
- if needed, place restrictions on the research,
- take any actions considered reasonably necessary that are consistent with REB policies and procedures, and to ensure the protection of the rights, safety, and well-being of participants in research conducted at MSVU

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

The REB 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. References

See References listed (if applicable)

7. Acknowledgements

The development of this document has benefited directly from similar documents made public by the Tri-Council, as well as several Canadian universities. In some instances, specific formulations drawn from these sources have been incorporated into this document. Specific iterations were drawn from the following:

- Standard Operating Procedures for Observational Health and Non-Clinical Trial Research Ethics Boards - N2/CAREB-ACCER REB SOPs – Canadian Association of Research Ethics Boards (retrieved June 2021)
- N2/CAREB-ACCER REB SOPs - N2 Network of Networks - Resources - N2 Canada (retrieved May 2021)

8. SOP History

SOP Number	Key Changes	Effective Date
REB.SOP.101	Extensive revisions - Implementation of new SOP outlining Authority and Purpose of the REB	July 1, 2021
REB.SOP.101	Original	February 2012

This Page is intentionally left blank.