

SOP 101.001

Title	Authority and Purpose
SOP Code	101.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy

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 the REB to assure that the rights and welfare of participants are protected;
4. State the authority of the REB.

2.0 SCOPE

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

3.0 RESPONSIBILITIES

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

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

The REB 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 The REB 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 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;
- 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 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 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 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 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 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.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 101.001		