Title	Authority and Purpose
SOP Code	101.004
Effective Date	15-May-2023

Site Approvals

Name and Title (typed or printed)	Signature	Date MM/DD/YYYY
Meera Sidhu, Research Ethics Manager	MSidhu	12/01/2023
Steven Smith, Deputy Vice-Principal Research		12/04/2023

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 regulations and guidelines.

3.0 RESPONSIBILITIES

The responsible 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 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 organization has authorized the REB to review research involving human participants conducted under the auspices of the organization.

5.1.2 The REB is established and empowered under the authority of the organization. The organization requires that all research involving human participants be reviewed and approved by an REB before the 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 participants participating in research.

5.2.2 The REB reviews ~~**and oversees**~~ **all** research **ethics applications** to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection.

5.2.3 ~~**These**~~ **Applicable regulations and guidelines** include, but are not limited to, the Food and Drugs Act and applicable Regulations, the International Council 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, and where applicable, US Federal Regulations.

5.3 Governing Principles

5.3.1 The REB is guided by the 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 has 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 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 US Regulations

The REB shall apply the requirements of the applicable US regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP101.001	15-Sept-2014	Original version
SOP101.002	08-Mar-2016	No revisions needed
SOP101.003	08-Oct-2019	5.2.3: ICH 'Conference' changed to 'Council'; Removed "Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013)
SOP101.004	15-May-2023	No revisions needed
SOP 101.004	1-Dec-2023	Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text