TRINITY WESTERN UNIVERSITY

SOP 101

TITLE	**101: Authority and Purpose**
SCOPE	The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

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

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

1.2 Define the purpose of the HREB;

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

1.4 State the authority of the HREB.

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

The HREB 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.

3.1 Statement of Organizational Authority

3.1.1 The organization has authorized the HREB to review research involving human participants conducted under the auspices of the organization;

3.1.2 The HREB 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 HREB prior to initiation of any research related activities.

3.2 Purpose of the HREB

3.2.1 The HREB's purpose is to protect the rights and welfare of human participants participating in research;

3.2.2 The HREB 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;

3.2.3 These include, but are not limited to, the Food and Drugs Act and applicable 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, Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013) and where applicable, US Federal Regulations.

3.3 Governing Principles

3.3.1 The HREB 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.

3.4 HREB Authority

3.4.1 The HREB is established to review all research involving human participants within its established jurisdiction;

3.4.2 The 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 the 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 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 HREB 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 HREB's jurisdiction.

3.5 Research Subject to US Regulations

The HREB 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.

4.0 REFERENCES

See References.

5.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 101	November 14, 2019	Original version