POLICY RESEARCH ETHICS REVIEW		Page 1 of 5
EXECUTIVE SPONSORSHIP Vice President, Quality	**INITIALLY RELEASED:** April 2005	**VERSION:** October 31, 2024

INTENT / PURPOSE

Fraser Health recognizes that human participation in research is necessary for advancement of knowledge and care. Research involving humans must always be conducted in accordance with the highest ethical standards in order to protect the rights, welfare and dignity of participants and ensure public confidence and trust.

The purpose of this policy is:

1. to promote a research environment in Fraser Health that upholds the highest ethical standards and respects the rights and safety of human participants.
2. to promote awareness of these standards among Fraser Health staff.
3. to establish an independent research ethics review process.

SCOPE

This policy applies to all research involving humans, as defined in the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2)[1], conducted under Fraser Health auspices and/or within Fraser Health jurisdiction.

Exclusions

This policy does not apply to the following:

- Research recruiting Fraser Health staff as research participants which falls outside of their prescribed work time and/or broad fiduciary responsibilities to Fraser Health.
- Research conducted by physicians with Fraser Health privileges exclusively in private clinics that are not affiliated with Fraser Health.
- The provision of research services by Fraser Health departments to research conducted outside of Fraser Health jurisdiction and auspices, as described in the Research - Operational Approval - Corporate Policy
- Any project that does not meet the criteria of research involving humans requiring REB review, as defined by TCPS 2.

POLICY

Statement of principles

Fraser Health adopts the core ethical principles of the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2):

- Respect for Persons
- Concern for Welfare
- Justice

These principles must guide the conduct of research involving humans as well as guide the Fraser Health Research Board (FHREB) in conducting the research ethics review and determining the ethical acceptability of a submission.

These principles are consistent with the ethical principles in the Declaration of Helsinkihttps://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/doh-oct2008/[2] of the World Medical Association, the Belmont Report (1979)Belmont Report (1979)[3] of the United States

National Commission for the Protection of Human Participants of Biomedical and Behavioral Research, and the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice 6(R2) Harmonisation.[4]

Mandate of FHREB
The FHREB is established and empowered under the authority of the VP responsible for research to review and maintain, on behalf of the institution, ongoing oversight of the ethical acceptability of all proposed or ongoing research involving humans. The FHREB shall conduct its activities in compliance with TCPS 2 and all applicable regulatory and legal requirements.

The FHREB is accountable to the institution for its research ethics review processes. However, in conducting its research ethics reviews, the FHREB must operate in an impartial manner, and without interference from the institution. The decisions of the FHREB with respect to any given research project are not subject to review by the institution or any other person except to the extent that such decisions may be reviewed through the established Reconsideration and Appeals Procedures.

The FHREB is responsible for determining the applicability of this policy and the scope of its jurisdiction.

Appointment of FHREB
The VP responsible for research appoints the FHREB and provides the necessary administrative and financial support and independence to fulfill its duties. The VP responsible for research may delegate the appointment of FHREB members to the FHREB Chair(s).

The composition of the FHREB membership must be consistent with the requirements of TCPS 2 and all applicable regulations.

Reporting Relationship of the FHREB
The FHREB shall provide a report to the Fraser Health Board of Directors Quality Committee on its activities on an annual basis.

Requirement of REB review
All research involving human participants must be reviewed and approved by the FHREB prior to initiation of any research-related activities. All research in which study procedures and/or data collection are ongoing must be submitted to the FHREB for renewal before the expiry date of the current certificate of ethical approval. Any proposed changes to the research project must obtain the approval of the FHREB before proceeding with these changes, except when necessary to eliminate an immediate hazard to a participant. The FHREB must then be immediately notified, and the modification submitted for consideration immediately thereafter.

REB review fees
All submissions to the FHREB are subject to review fees. Fees are waived for studies that are unfunded, funded by granting agencies that do not allow funds to be applied to REB fees, or grant-in-aid funded projects in which a for-profit entity will not have access or intellectual property rights to the study data.

The Principal Investigator is responsible for payment of REB review fees, which are due upon invoice. The FHREB may withhold review of all submissions by Principal Investigators with outstanding fees.

Multi-jurisdictional Review
In accordance with TCPS 2 Chapter 8 – Multi-Jurisdictional Research, Fraser Health may adopt alternate models of research ethics review for multi-jurisdictional research, including serving as or accepting direct reciprocity from another research ethics board of record, in order to facilitate collaborative research involving investigators, participants and/or resources from more than one institution, and to avoid unnecessary duplication of effort.

For above minimal risk studies, the adoption of an alternative review model must be based on an official ethical review agreement. This agreement must ensure all institutions involved adhere to TCPS 2 and all applicable regulatory and legal requirements.

Prior to the adoption of any alternative review model, the FHREB must be satisfied with the manner in which the other institution conducts its ethical reviews.

Researcher Responsibilities
Researchers hold the primary responsibility for the ethical conduct of the study and the protection of the rights and safety of human participants. Researchers are expected to comply with this policy and all applicable ethical guidelines.

Researchers are responsible for:
1. obtaining ethical approval for all research involving humans prior to the commencement of any research procedures,
2. maintaining in good standing the ethical approval for the entirety of the research, in accordance with FHREB requirements,
3. conducting the research in accordance with the REB-approved protocol and other application materials,
4. conducting the research in accordance with the TCPS 2 and all other applicable regulatory and legal requirements,
5. conducting the research in accordance with all applicable Fraser Health policies, including requirements for the privacy and security of personal information,
6. Adhering to all applicable reporting requirements,
7. Declaring any perceived, potential, or real conflicts of interest to the REB,
8. Paying all REB review fees applicable to the research in a timely manner.

The Principal Investigator is ultimately responsible for the conduct of research team members and should ensure team members involved in the research are aware of this policy and all applicable requirements for the ethical conduct of the research.

Responsibilities of the Administrative Supervisor
Initial applications to the FHREB must include a signed confirmation from the Principal Investigator's administrative supervisor that the Principal Investigator has the appropriate qualifications, skills, and resources to conduct the research. In the event the Principal Investigator's immediate administrative supervisor is not available, or is also a member of the study team, the next senior administrator for that person should provide the signed confirmation.

Non-Compliance
The FHREB is responsible for the initial investigation and management of reports of researcher non-compliance with this policy and/or failure to conduct research in accordance with the FHREB approval. The FHREB may take corrective actions as necessary. Serious or repeated instances of non-compliance may be considered research misconduct under the Research Integrity - Corporate Policy, and may require reporting to the research funders, sponsors, applicable regulatory agencies, and the Fraser Health executive.

DEFINITIONS

Above minimal risk: Research in which the probability and magnitude of possible harms implied by participation in the research are greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Auspices: For the purposes of this policy, research under Fraser Health auspices includes:
1. Research conducted by Fraser Health staff, whether as principal investigator or co-investigator.
2. Research sponsored by Fraser Health.
3. Research in which Fraser Health administers any portion of the funding.

Board of Record: an REB that, by agreement between the institutions involved in a multi-jurisdictional research study, will serve as the primary authority for the ethical oversight of the project.

Direct Reciprocity: The acceptance, with an agreed level of oversight, the research ethics review and decision of the board of record for a multi-jurisdictional research project.

Ethical Review Agreement: an agreement between Fraser Health and another research institution or organization that authorizes an alternative model or models for ethics review of Research Involving Human Participants. Such agreements may or may not be reciprocal in nature.

Human Biological Materials: human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials and stem cells.

Jurisdiction: Research within Fraser Health jurisdiction includes:
1. Research in which any part of the study procedures occurs in Fraser Health owned, operated, or contracted facilities, or uses Fraser Health equipment and/or resources.
2. Research recruiting persons we serve as participants.
3. Research collecting personal information, data, and/or biological specimens held or maintained by Fraser Health.
4. Research recruiting Fraser Health staff and/or volunteers as participants.

Multi-jurisdictional research: Research conducted under the auspices and/or the jurisdiction of multiple institutions and which requires ethics review by more than one of institutions' research ethics boards.

Participant: An individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s). Also referred to as a "human participant," and in other policies/guidance as "subject" or "research subject."

Principal Investigator: The researcher who is responsible for the ethical conduct of the research, and for the actions of any member of the research team at a local site.

Research: an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation, including pilot studies. The term "disciplined inquiry" refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

Research Involving Humans: Research involving living human participants and/or human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials, and stem cells. This applies to materials derived from living and deceased individuals.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a research project or clinical trial.

REFERENCES

1. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 – 2022) [Internet] Available from: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

2. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association [Internet] Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

3. The Belmont Report [Internet] Available from: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Integrated Addendum to ICH E6(R1): Guidelines for Good Clinical Practice 6(R2) [Internet] Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

RELATED RESOURCES:

- Research Corporate Policy
- Research - Collection, Use and Disclosure of Personal Information for Research-related Purposes - Corporate Policy
- Research Integrity- Corporate Policy
- Research – Operational Approval – Corporate Policy

DATE(S) REVISED / REVIEWED SUMMARY

Version	Date	Comments / Changes
1.0	April 2005	Initial policy released
2.0	January 2007	Revision
3.0	June 2007	Revision
4.0	May 2012	Revision
5.0	January 2014	Revision
6.0	August 2017	Revision
7.0	October 2024	Revision