POLICY RESEARCH		Page 1 of 7
EXECUTIVE SPONSORSHIP Vice President, Quality	**INITIALLY RELEASED:** June 2005	**VERSION:** October 31, 2024

INTENT/PURPOSE

Fraser Health recognizes the fundamental importance of research for improving its service delivery, patient outcomes, and quality of care. To this end, Fraser Health has a commitment to support evidence-based research and knowledge translation, and to ensure transparency of the research process and administrative requirements to the public, regulatory authorities, and Fraser Health staff.

The purpose of this policy is to:

1. Describe the authority and obligations under which research activities can be conducted in Fraser Health jurisdiction and/or under Fraser Health auspices.
2. Define the criteria for permitted research.
3. Describe the Fraser Health administrative oversight for research.

SCOPE

This policy applies to the conduct of research in Fraser Health jurisdiction and/or under Fraser Health auspices as outlined below:

- The research is sponsored by Fraser Health, or; the research is conducted by any Fraser Health staff, under their Fraser Health affiliation as principal or co-investigator.
- The research is recruiting any Fraser Health staff, persons we serve, and/or volunteers as research participants.
- The research involves the collection of personal information held or maintained by Fraser Health about any people we serve, volunteers, and/or staff.
- The research involves the use of any Fraser Health resources or facilities, including contracted services and facilities.
- Any portion of the research funding is administered by Fraser Health.

This policy encompasses and applies to all aspects of research activities, including planning activities, data collection, knowledge translation, dissemination, and implementation. Quality improvement and evaluation projects that do not contain a research component are not included in the scope of this policy.

POLICY

1. Roles and Responsibilities

1.1 Vice President (VP) Responsibilities

The VP responsible for research may delegate these or a portion of these duties to the Executive Director Learning and Research or others as appropriate but remains responsible for the oversight of the policy:

- the development and implementation of this policy.
- approving proposals for sponsored research and grant funding on behalf of Fraser Health.
- negotiating and executing research agreements on behalf of Fraser Health.
- institutional sign off on the Agreement on the Administration of Agency Grants and Awards by Research Institutions.

1.2 Director, Department of Evaluation and Research Services (DERS) Responsibilities

- Appointed by the institution to provide institutional authorization for all research conducted in Fraser Health to ensure compliance with all relevant regulatory, fiduciary, and policy requirements. This authorization will only be issued once all applicable sub-approvals are satisfied.
- Administrative oversight of all research at Fraser Health.
- Determining the scope and applicability of this policy in relation to specific research projects.

The Director of DERS may sub-delegate any responsibilities and authorities as required.

1.3 Researcher Responsibilities

- All Fraser Health staff who conduct research within the scope of this policy are required to comply with this policy.
- Researchers conducting research in/or under the auspices or jurisdiction of Fraser Health are required to be familiar with and comply with all applicable policy, regulatory, legal, and fiduciary requirements.
- The principal investigator (PI) shall be responsible for:
  - ensuring the terms and conditions of all awarded research grants, research contracts and/or confidentiality agreements are complied with at all times,
  - the conduct of all co-investigators, sub-investigators, students, trainees, and research staff assisting in the conduct of the research,
  - obtaining all required authorizations and approvals for the research,
  - ensuring appropriate study documentation,
  - maintaining research records in a secure location in accordance with all regulatory, contractual, and/or funding obligations, and in accordance with the Research Integrity - Corporate Policy.
  - ensuring standard operating procedures are in place for clinical trials that adhere to the applicable legislative and regulatory requirements, and to good clinical practices.
- Results of research undertaken by Fraser Health researchers shall be made public and adhere to the publication policies of the granting agencies and/or research contract, where applicable.
- Fraser Health researchers shall list “Fraser Health Authority” as the professional affiliation or institution on all publications resulting from research conducted under the auspices of Fraser Health.
- Researchers agree that the nature of their research activities, the funding received, and source of funds may be summarized in Fraser Health communications.
- Researchers are responsible for ensuring their research meets the highest integrity, scientific, ethical and professional standards, including considerations of equity, diversity and inclusion (EDI) principles and Indigenous cultural safety approaches and guidance[1].

2. Permitted Research

2.1 Criteria for Permitted Research

The PI for any research conducted within the scope of this policy must be:

- A Fraser Health staff member; or,

- A researcher with an academic appointment at a recognized post-secondary institution who has obtained affiliated status with Fraser Health.
- External PI's must have a Fraser Health staff member serving as a co-investigator on the study team.

Research conducted under the scope of this policy must be compliant with all applicable requirements and regulations, including the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)[2], Health Canada Food and Drug Regulations [3] and Medical Device Regulations[4], International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (ICH GCP)[5], and all other Fraser Health policies.

The following may only occur after a Letter of Authorization to Conduct Research (LOA) has been issued by the Director of DERS:

- Research involving humans as per the Research - Ethics Review - Corporate Policy.
- Research occurring in Fraser Health facilities or using Fraser Health resources.
- The release of research funding held at Fraser Health.

2.2 Research Not Permitted

The following types of research are not permitted:

- Research conducted by students or trainees as PI.
- Research conducted by external researchers who do not have an affiliation agreement with Fraser Health.
- Research involving animals or biohazardous substances other than approved radioisotopes.
- Research in which an intention to fully publish the results is prohibited in a contractual agreement with the sponsor.
- Marketing research that offers no reasonable expectation of patient or public benefit.
- Research that is contrary to Fraser Health's purpose, values, and vision, or poses undue reputational risk to the health authority.

For exemptions to any of the above, the VP (or designate) responsible for research must provide special authorization.

2.3 Clinical trials

- Regulated Clinical Trials involving the people we serve as participants must be conducted by a physician with Fraser Health privileges under their Fraser Health affiliation as the qualified investigator.
- External principal investigators (regardless of affiliation status with Fraser Health) are not permitted to conduct regulated clinical trials with Fraser Health patients, clients, tenants, or facility residents.
- External principal investigators (regardless of affiliation status with Fraser Health) are not permitted to conduct unregulated clinical trials with Fraser Health inpatients or facility residents unless special permission has been granted by the VP (or designate) responsible for research.
- Fraser Health shall be listed as the site for all clinical trials conducted in Fraser Health jurisdiction or under Fraser Health auspices.

- Regulated clinical trials initiated by Fraser Health investigators and/or sponsored by Fraser Health must implement a quality management system in consultation with the Clinical Trials and Business Development Office.

3. Research Administration

DERS provides administrative oversight and support for research on behalf of Fraser Health.

3.1 Fraser Health shall have the authority to put into place procedures for monitoring ongoing research.

3.2 Fraser Health shall maintain research records related to its administrative functions in accordance with applicable regulatory, legal, fiduciary, and policy requirements.

3.3 Research Funds

- All applications for external research funding with Fraser Health as the host institution submitted by Fraser Health staff must be approved by the VP (or designate) responsible for research prior to submission. DERS is responsible for administering the process of obtaining such approval.
- Fraser Health staff shall notify DERS of any proposals being submitted for funding to external agencies in which Fraser Health is not the host institution.
- Research funds held by Fraser Health are not the property of any individual researcher and are administered in accordance with Fraser Health policy.

3.4 Equipment

- Subject to the terms of grant funding agreements, equipment and materials purchased or collected with grant funding from a non-commercial funding agency shall belong solely to Fraser Health.
- Proceeds from the sale of any grant-funded equipment or materials shall be used for research-purposes only.
- Fraser Health researchers may request permission to take unexpended grant equipment or other materials purchased with grant funds when moving to another Canadian institution.
- Equipment not in use by the grant recipient shall be made available for use by other Fraser Health personnel for their research. Fraser Health may charge fees to these users should there be a requirement to recover direct costs incurred.
- DERS shall maintain a record of equipment and other materials obtained via grant funding awarded to Fraser Health.

3.5 Research Accounts

- All research awards and funds received by Fraser Health staff acting in their capacity as a Fraser Health PI for a specific study shall be held in a designated research account under DERS.
  - Exceptions may be granted for funds received by physicians with Fraser Health privileges for the conduct of industry sponsored research.
- Fraser Health PI shall abide by assigned responsibilities for their research cost centre(s).
- Unspent grant funds shall be returned to the grant funder. If the funder does not require the return of unspent funds, the funds will be administered by DERS in accordance with Fraser

Health Finance requirements. Unspent funds will be used by Fraser Health for research purposes.

3.6 Research Agreements

- Research that involves an external party(ies) shall require a written agreement that defines the obligations of Fraser Health and the external party(ies). This can apply to academic and other health authority-based researchers and industry sponsors who require access to Fraser Health sites, patients and/or data to conduct research, industry sponsors that require a confidential review of a protocol, funding transferred to or from an academic institution, and installation of equipment for research purposes when funded externally.

3.7 Ownership of Results and Publication

- Fraser Health researchers shall reach a mutual understanding about ownership of the research results with the research collaborators regardless of the source of funding, before research is undertaken.
- The Fraser Health PI shall endeavor to publish and disseminate through appropriate channels the results of the research.
- All researchers shall disclose any potential intellectual property arising from their research – as per Research - Intellectual Property - Corporate Policy

DEFINITIONS

Auspices: Research conducted under the protection, endorsement, or support of Fraser Health, including:

1. Research conducted by Fraser Health staff whether as principal investigator or co-investigator.
2. Research sponsored by Fraser Health.
3. Research in which any portion of the funding is administered by Fraser Health.

Clinical Trial: A clinical trial is a research study involving human participants that are prospectively assigned to one or more interventions to evaluate the safety and/or effects of those interventions on health-related biomedical or behavioural outcomes. Interventions include, but are not limited to, drugs, vaccines, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products (NHPs), process-of-care changes, preventive care, manual therapies, and psychotherapies.[6,7]

External Principal Investigator: A principal investigator who does not hold a formal appointment (i.e. staff or physician who has been granted privileges by the Fraser Health's board to practice in the facilities and programs owned or operated by Fraser Health) with Fraser Health. External PIs must sign an affiliation agreement with Fraser Health in order to conduct research within Fraser Health jurisdiction.

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.

Knowledge Translation: A dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve people's health and provide more effective health services and products and strengthen the health care system.[8]

Regulated clinical trials: Clinical trials are defined as falling under the scope of Part C, Division 5 of the Health Canada Food and Drug Regulations and/or US Food and Drug Administration (FDA) policy.

Research: An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. 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.[2]

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a research project or clinical trial.[5]

Quality Management System: A structured framework and set of processes and procedures designed to manage the quality of research throughout all stages of the research project to ensure that it consistently meets and exceeds the institutional research standards of integrity and reliability of data generated, participant safety, and relevant regulations such as the ICH-GCP.

Unregulated clinical trials: Clinical trials which are not subject to Health Canada and/or US FDA regulations.

REFERENCES

1. Indigenous Research Ethics [Internet]. Available from: https://healthresearchbc.ca/research-ethics-bc/why-research-ethics/indigenous-research-ethics/
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) [Internet]. Available from: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html)
3. Health Canada Food & Drug Regulations [Internet]. Available from: https://laws-lois.justice.gc.ca/eng/Regulations/c.r.c.,_c._870/index.html
4. Health Canada Medical Device Regulations [Internet]. Available from: https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/
5. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (ICH GCP) [Internet]. Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
6. Canadian Institutes of Health Research Glossary of Funding Related Terms [Internet]. Available from: https://cihr-irsc.gc.ca/e/34190.html
7. National Institutions of Health Central Resource for Grants and Funding Information: NIH's Definition of a Clinical Trial [Internet]. Available from: NIH's Definition of a Clinical Trial | grants.nih.gov
8. Canadian Institutes of Health Research Guide to Knowledge Translation Planning at CIHR: Integrated and End-of-Grant Approaches. [Internet]. Available from: https://cihr-irsc.gc.ca/e/documents/kt_lm_ktplan-en.pdf

RELATED RESOURCES

- Research – Research Ethics Review – Corporate Policy
- Research – Research Operational Approval – Corporate Policy
- Research - Collection, Use and Disclosure of Personal Information for Research Purposes – Corporate Policy
- Research – Research Integrity – Corporate Policy
- Research – Intellectual Property - Policy
- Clinical Research Overhead Rates – Policy

DATE(S) REVISED / REVIEWED SUMMARY

Version	Date	Comments / Changes
1.0	June 2005	Initial policy released
2.0	June 2007	Revision
3.0	October 2009	Revision
4.0	November 2010	Revision
5.0	May 2012	Revision
6.0	January 2013	Revision
7.0	August 2017	Revision
8.0	September 2021	Revision
9.0	October 2024	Revision - removal of SOP (Standard Operating Procedure) content