

<u>POLICY</u> COLLECTION, USE AND DISCLOSURE OF PERSONAL INFORMATION FOR RESEARCH-RELATED PURPOSES		Page 1 of 6
<u>EXECUTIVE SPONSORSHIP</u> Vice President, Quality	<u>INITIALLY RELEASED:</u> June 2005	<u>VERSION:</u> October 31, 2024

INTENT / PURPOSE

As a public body, Fraser Health has legal and ethical responsibility to manage information within its custody and control in accordance with applicable legislation while also recognizing the rights of individuals to determine how and when their [personal information](#) is shared. Fraser Health recognizes the importance of personal health information in research for improving service delivery, patient outcomes, and quality of care.

The purpose of this policy is to establish the authority, administrative oversight, and mechanisms for the collection, [use](#), and [disclosure](#) of personal information by Fraser Health for research-related purposes. This policy ensures research participant [privacy](#) and confidentiality is protected through compliance with applicable regulations, standards, and policies.

SCOPE

This policy applies to all research projects that request access to personal information, including medical records, administrative data, and tissue samples, in the custody and control of Fraser Health.

POLICY

1. Authority

Fraser Health is responsible for the appropriate handling of personal information in the custody and control of the health authority. The institution is permitted to disclose personal information for [research purposes](#) where authorized to do so by applicable legislation and health authority policy.

- a. Fraser Health may collect, disclose, store or use personal information within its custody and control for research purposes where that activity complies with applicable [legislation and policies](#), including but not limited to [Freedom of Information and Protection of Privacy Act \(FoIPPA\)](#)¹, [Personal Health Information Access and Protection of Privacy Act \(eHealth Act\)](#)², [Pharmaceutical Services Act](#)³, and the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS 2\)](#)⁴.
- b. Requests for personal information for research purposes are subject to operational capacity and other conditions by Fraser Health.

2. Administrative Oversight

- a. Privacy Department Responsibilities: The Fraser Health Privacy Department is responsible for ensuring Fraser Health complies with privacy legislation and regulations when releasing of personal information for research purposes. This includes:
 - i. Administering, reviewing, and approving the [Research Data Access Application and Agreement \(DAA\)](#) for all collection, use and disclosures of personal information for research purposes,
 - ii. Determining when a [Privacy Impact Assessment \(PIA\)](#) is required,
 - iii. Managing the response protocol for all real, suspected, and/or potential research privacy breaches involving personal information released by Fraser Health in accordance with the [Fraser Health Managing Privacy Breaches - Corporate Policy](#), and;
 - iv. Advising employees and departments about how to comply with [FoIPPA](#).

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- b. Fraser Health Research Ethics Board (REB) Responsibilities: The Fraser Health REB is responsible for the ethical review of all human participant research within Fraser Health jurisdiction and/or under Fraser Health auspices. This review includes:
 - i. Provisions for safeguarding information throughout all stages of the research life-cycle, including but not limited to recruitment, screening, data collection, transfer, storage and destruction,
 - ii. Foreseeable privacy and confidentiality risks arising from the research, and
 - iii. Appropriateness of screening and consent procedures, including consent documentation and whether an alteration of normal consent procedures is ethically justifiable, where applicable.
- c. Fraser Health Data Stewards are responsible for:
 - i. Determining operational impact, feasibility, timelines, and associated costs (if applicable) for the information release,
 - ii. Validating that projects have the appropriate approvals, including a DAA, PIA and/or [Security Threat and Risk Assessment \(STRA\)](#) where necessary, before releasing information on behalf of Fraser Health, and
 - iii. Ensuring the information is released using a secure data transfer process after the Letter of Authorization to Conduct Research in Fraser Health has been issued for the research project.
- d. Fraser Health Responsibilities: Fraser Health is responsible for providing secure platforms for research data storage and transfer in compliance with best practices and regulatory requirements.

3. Researcher responsibilities

Researchers accessing personal information for research purposes must abide by the following responsibilities:

- a. Safeguard the personal information entrusted to them and not misuse or wrongfully disclose it,
- b. Only collect, disclose, store, or use personal information necessary to fulfill the research objectives and in a manner that complies with relevant privacy, confidentiality and security measures approved by the REB and Fraser Health Privacy Department,
- c. Employ measures to de-identify personal information collected for the research, where appropriate at the earliest reasonable time at which it can be accomplished,
- d. Report privacy breaches to the Fraser Health Privacy Department and notify the REB that such reporting has occurred within two (2) business days of becoming aware of any such breach,
- e. Destroy personal information provided by Fraser Health when no longer required for the approved research purpose in accordance with the approved data retention period in the REB application as well as applicable regulatory and policy data retention requirements, and
- f. Be available to review data handling procedures used, upon request by Fraser Health, to ensure compliance with data security best practices, legal requirements, and Fraser Health policies.

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- a. Fraser Health may disclose personal information within its custody and control for a research purpose under the following conditions:
- i. The Letter of Authorization to Conduct Research at Fraser Health has been issued for the project, and
 - ii. the information was collected directly from the individual the information is about for the express purpose of conducting the relevant research project (consistent use), or
 - iii. the individual the information is about has consented, in the prescribed manner, to the disclosure, or
 - iv. for a research purpose without individual consent or where consistent use is not present, under the conditions outlined by [FoIPPA](#). The release of personal information without individual consent must meet rigorous standards of privacy and confidentiality, and may only occur where:
 - The research purpose cannot be accomplished unless the information is disclosed in individually identifiable form, and,
 - Fraser Health has approved conditions related to:
 - confidentiality and security,
 - the removal or destruction of individual identifiers at the earliest reasonable time,
 - the prohibition of subsequent use or disclosure of the information in individually identifiable form without the express authorization of the Fraser Health, and,
 - the Principal Investigator has signed a DAA with Fraser Health, and
 - the REB has approved the alteration of normal consent procedures in accordance with TCPS 2 and other regulatory requirements, and
 - The information is disclosed on condition that it not be used for the purposes of contacting a person to participate in the research unless:
 - The research is in relation to health issues, and
 - Approval for this use is obtained by the Information and Privacy Commissioner for BC.
- b. Release of tissue and/or medical records for non-Fraser Health research and/or clinical trials led by external researchers:
Fraser Health may release tissue originally obtained for the purposes of providing medical care or medical records for research participants enrolled in a study and/or clinical trials that does not fall under the auspices or within the jurisdiction as defined by the [Research – Ethics Review – Corporate Policy](#) under the following conditions:
- The research has a valid Certificate of Approval from a TCPS 2 compliant REB,
 - Consent has been obtained from the participant or the participant’s substitute decision maker for the release of the tissue or personal information and a copy of the signed consent form has been provided to the Fraser Health Data Steward. For studies in which the REB has approved a waiver of consent, evidence of the approved waiver must be provided to the Fraser Health Data Steward,
 - The release of tissue or personal information is compliant with [FoIPPA](#) and any other application regulations.

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- c. Use of personal information for research within Fraser Health: The release of personal information to [Fraser Health researchers](#) is considered a use rather than disclosure. Fraser Health may authorize the use of personal information for research under the following conditions:
 - i. The personal information was originally collected for the research purpose, or
 - ii. Consent from the participant is required for the change in use when the personal information was not originally collected for a research purpose. If consent will not be sought, the conditions in section 4.a(iii) for the disclosure of personal information held by Fraser Health for a secondary research purpose must be met, and
 - iii. the Letter of Authorization to Conduct Research at Fraser Health has been issued for the project.
- d. Research involving surveys: Research survey projects collecting personal information from research participants have been reviewed by the REB for [FoIPPA](#) compliance may be exempted from additional privacy review at the discretion of the Fraser Health Privacy Department. Research survey projects may only commence once the Letter of Authorization to Conduct Research at Fraser Health has been issued for the project.
- e. Research projects involving new software, information systems, or technologies that interface with Fraser Health information systems: A risk assessment will be conducted to determine if a PIA and/or STRA is required for such projects.

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.

Data Access Application and Agreement (DAA): An agreement between the Principal Investigator and the Fraser Health Privacy Department required for all research requesting collection, use, or disclosure of personal information under Fraser Health custody and control for secondary use purposes. This agreement includes privacy protective measures addressing security and confidentiality, removal or destruction of identifiers, prohibitions against further use without approval or disclosure beyond research, and an undertaking to comply with the approved conditions, [FoIPPA](#), and policies and procedures of Fraser Health.

Disclosure: Means to reveal, show, expose, provide copies of, sell, give, or tell (personal or non-personal information or records). Disclosure may occur either as a routine release of information in the absence of a requestor or in response to a formal request under the Act.⁵

Fraser Health Researcher: A researcher who is Fraser Health staff and conducting the research in this capacity.

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.

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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.

Personal Information: Means recorded information about an identifiable individual other than business contact information. Information can be in paper, electronic, or photographic form. Personal Information can exist in its raw form, containing personal identifiers, or be processed to remove identifiers when it is collected for the research (De-Identified Personal Information). Tissue may also be treated as Personal Information under this policy, in cases where the laboratory research methods and/or storage conditions pose a reasonable risk of re-identification of the individual from whom it was derived. Personal Information includes de-identified data that may not contain individual names or identifiers but where individuals can be re-identified by a third party.

Privacy: An individual's right to be free from intrusion or interference by others. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information (TCPS 2 Chapter 5), or where a Research Ethics Board has deemed the privacy protections of the research to be appropriate.

Research Purposes: Any purpose related to the research project, including but not limited to screening, recruitment, data collection, data transfer and storage, and knowledge dissemination.

Privacy Impact Assessment (PIA): An information management tool that helps to determine whether new technologies, information systems, programs, initiatives, projects, strategies or proposals meet basic privacy requirements. The PIA measures compliance with the BC Freedom of Information and Protection of Privacy Act and assesses risk.

Security Threat Risk Assessment (STRA): The overall activity of assessing and reporting security risks for an information system to help make well informed risk-based decisions. An STRA also documents risk ratings and planned treatments.

Use: Use of personal information means employing it to accomplish the public body's objectives; for example, to administer a program or activity, to provide a service or to determine someone's eligibility for a benefit or suitability for a job.⁵ ([FoIPPA Manual](#)).

REFERENCES

1 [Freedom of Information and Protection of Privacy Act \(FoIPPA\)](https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/12022_01#section26) [Internet] Available from: https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/12022_01#section26

2 [Personal Health Information Access and Protection of Privacy Act \(eHealth Act\)](https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/08038_01) [Internet] Available from: https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/08038_01

3 [Pharmaceutical Services Act](https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/08038_01) [Internet] Available from: https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/08038_01

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

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5 FoIPPA Policy & Procedures Manual [Internet] Available from:

<https://www2.gov.bc.ca/gov/content/governments/services-for-government/policies-procedures/foippa-manual>

RELATED RESOURCES

- [Research – Corporate Policy](#)
- [Research – Research Ethics Review – Corporate Policy](#)
- [Research – Operational Approval – Corporate Policy](#)
- [Research Integrity Policy](#)

DATE(S) REVISED / REVIEWED SUMMARY

Version	Date	Comments / Changes
1.0	June 2005	Initial policy released
2.0	March 2014	Revision
3.0	June 2018	Revision
4.0	October 2024	Revision