

**THE COLLECTION, USE AND DISCLOSURE OF
PERSONAL INFORMATION FOR RESEARCH-
RELATED PURPOSES**

<u>AUTHORIZATION</u>	<u>DATE APPROVED</u>	<u>DATE REVISED</u>
Vice President, Academic Development and Clinical Innovation	June 21, 2005	

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1. PURPOSE

As a public body and a [Steward](#) of personal information, Fraser Health [FH]¹ is accountable for the protection of the [Privacy](#) and [Confidentiality](#) of all [Personal information](#) under its custody and control in accordance with existing legislation, public expectations and internationally accepted fair information practices. This includes all personal information collected either directly from individuals in the provision of their care at FH, collected indirectly from other care providers and institutions during the provision of an individual's care at FH, and/or collected by [FH Researchers](#) specifically for [Research](#) purposes.

British Columbia's "*Freedom of Information and Protection of Privacy Act*" (October 21, 2004) [FOIPPA](#) provides a framework for managing the circumstances under which personal information may be collected, used, disclosed and retained for research purposes by all provincial public bodies. Other applicable best practice standards to which FH adheres include the Canadian "*Tri-Council Policy Statement: The Ethical Conduct for Research Involving Human Subjects*" [TCPS](#) (1998) and the Canadian Institute for Health Research "*Best Practices for Protecting Privacy in Health Research*" [CIHR](#) (2004).

The purpose of this policy is to ensure that throughout the conduct of research-related activities that the collection, use and disclosure of the personal information of research [Subjects](#) is protected by complying with the requirements of FOIPPA and meeting the standards of the TCPS.

This policy is supported by the following FH policies:

- *The Ethical Conduct of Research and Other Studies Involving Human Subjects* (Approved April 2005) [Ethics](#),
- *Privacy and Security of Personal Information* (Approved October 2003) [CSPI](#), and;
- *Audit of Electronic Health Information Access* (Approved April 2005) [Audit](#).

For the purposes of this policy, all definitions are found in Section 5 [Definitions](#). All references are found in Section 6 [References](#).

¹ Fraser Health will be used throughout this policy and denotes the Fraser Health Authority.

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1.1. Definition of Personal Information

Personal information is defined by FOIPPA as any recorded information about an identifiable individual other than contact information. Information can be in paper, electronic or photographic form, or as tissue² about which can reasonably be said to identify an individual.

Examples of personal information include, but are not limited to:

- name, address, or telephone number [business contact information is not included],
- race, national or ethnic origin, colour or religious beliefs or associations,
- age, sex, sexual orientation, marital status or family status,
- an identifying number, symbol or other particular assigned to the individual, such as date of birth, PHN, MRN or any organizational and/or department number such as lab number or surgical number,
- fingerprints, blood type or inheritable characteristics,
- health care history including information about disabilities, medications [e.g. from Pharmacare databases], tissue [including blood and DNA], outcome data from Provincial registries,
- education, financial, criminal or employment history,
- anyone else's [recorded] opinions about the individual,
- the individual's [recorded] personal views or opinions except if they are about someone else.
- tissue [living and dead, including blood and DNA] which has been collected for any purpose, including wet tissue, frozen tissue, paraffin blocks including tissue and slides with tissue.

2. PHILOSOPHY

Fraser Health [FH]³ recognizes that although the participation of human subjects Subject is indispensable in order to conduct research that has the potential to

² Source: Office of the B.C. Privacy Commissioner, June 2005

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benefit society as a whole, individual privacy rights must be protected while advancing appropriate and efficient information sharing to further research goals.

FH recognizes that the right of privacy includes an individual’s right to determine with whom they will share information and to know of, and exercise control over access, collection, use, disclosure of personal information about them. The right of privacy is exercised by providing consent.

FH believes that the protection of personal information that is used for research purposes is a fundamental and integral part of every research process. FH is therefore committed to ensuring that privacy principles are upheld through the implementation of responsible personal information management [PIM](#) and [Security](#) practices.

2.1. Statement Of Privacy and Confidentiality Principles

- i. Voluntary and informed [Consent](#) from legally competent individuals or their legally authorized representatives [Legal Rep](#), is a fundamental principle in research involving humans, and is specifically required for the use of their personal information. Consent reduces the risk of a breach to the individual’s privacy because this is an indication that the individual has decided to actively opt in to research activities which therefore establishes the researcher’s right to use the individual’s personal information in the manner defined in the consent form.
- ii. Consent for use of data for secondary purposes is obtained to ensure that individuals agree that the data they provided for their *Care* can also be used for *Research*. Consent of the individual for the use of this type of data for *Research* establishes the right to use data collected for *Care* for the secondary purpose of Research.
- iii. Whereas consent for the use of an individual’s personal information must be obtained to ensure that an individual’s right to privacy is protected, the confidentiality, integrity and availability of that data information must also be protected when used for research purposes. Personal information is

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considered to be highly sensitive and requires security⁴ safeguards that protect the integrity, availability and confidentiality of the information and that are commensurate with the sensitivity and level of risk to the individual if disclosed without appropriate authorization.

- iv. Limiting collection to the specific information required to fulfill the research objective forms a foundation to ensure that the research subject is not asked to contribute unnecessary and frivolous information. Collection of unnecessary information constitutes a breach of the collection principle and potentially a risk to the individual.
- v. The collection and use of personal information should adhere to the principle of maximum anonymity with minimum disclosure to protect the confidentiality of the personal information.

3. POLICY

3.1 Scope

This policy applies to:

1. the collection, use and disclosure of all personal information, including information contained in electronic databases/data warehouses, Research [Registries](#), paper records and tissue repositories, for which either FH or a [FH Researcher](#) is considered the information [Steward](#), and which is collected either:
 - 1) directly for research purposes from research subjects, or,
 - 2) indirectly from sources of information that were originally collected for purposes other than research, whether in FH's custody or not.
2. all personnel involved in collecting, using, retaining, disclosing and/or destroying personal information in the custody of FH or under the direction of the FH Principal Investigator for research purposes. Personnel may include FH employees, affiliated researchers, privileged physicians, other clinical staff, third party collaborators/sponsors, trainees, students, post-doctoral fellows and volunteers.

⁴ ISO 17799: Code of Practice for Security Management is the internationally accepted security management standard.

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3. all FH research activities including both retrospective and prospective research and the development of research registries.

3.2 Accountability and Stewardship

a. All paper documents or electronic storage media containing personal information used for research purposes are the property of FH but the information belongs to the person about whom the information is recorded.

b. FH data stewards have the responsibility to challenge requests for release of any personal information if there is uncertainty about any of the requirements being met.

3.3 Right to Refuse

a. Individuals have the right to refuse to have their personal information, originally collected for care or other purposes, used for research purposes.

b. Refusal of consent for the collection, use and disclosure of information shall not in any way be tied to treatment for any individual.

c. Where consent has been refused, individuals cannot be asked to sign that they have refused as this breaches confidentiality.

3.4 Defined Purposes

Personal information collected by a FH researcher shall be used solely for the purposes described in the FH Research Ethics Board [REB] approved research protocol and to which the research subject has consented.

3.5 Consent

a. Written, Informed Consent for the collection, use and/or disclosure of any personal information for research, before such collection, use and/or disclosure is made either to FH shall be obtained from the individual whose identifiable personal information is required for a research study as specified in the FH Policy "The Ethical Conduct of Research-related Activities Involving Human Subjects" (Approved 2005 April 12). This requirement applies to:

- the collection of information directly from the research subject during their participation in a research study, and;

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- the collection of information originally obtained for a purpose other than research, such as for care.
- b. The consent shall include detailed information on what records shall be collected and describe any data linkage if this is also part of the study.
- c. Access to identifiable personal data for research without consent shall be subject to specific legal requirements under the B.C. Freedom of Information and Protection of Privacy Act and the approval of the FH REB for the consent waiver.

(i) Chart Reviews

FH shall permit chart reviews to be carried out recognizing that it may be virtually impossible to examine charts in a de-identified form and in so doing requires that access to the charts shall be controlled with the application of strict security procedures.

(ii) Release of Tissue

1. If the tissue required is from a deceased individual and if the tissue is identifiable in that the External Researcher is requesting tissue from specified individuals, then consent from the next of kin must always be obtained by the External Researcher unless a waiver of consent is provided by the External Researcher's REB.
2. Tissue which is not identifiable in any way [i.e. anonymous] does not require consent.

3.6 Revocation of Consent

- a. Consent for the use of personal information for research purposes is revocable such that when consent is revoked by the research subject, their personal information shall no longer be used for research purposes. Data used prior to revocation is kept as per retention guidelines and remains available to support questions or investigations related to the integrity of the study and/or to provide an audit trail for clinical trials research if applicable.
- b. Procedures for revoking consent must be made available with the consent form given to patients.

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3.7 Limiting Collection

a. The indiscriminate collection of personal information with or without consent is strictly forbidden. The collection of personal information for a research study shall be limited to that needed to fulfill previously defined purposes of the research study. Researchers shall not collect data which cannot be justified to fulfill the research purpose/objectives, whether collected from the individual directly or indirectly; nor shall FH disclose data which cannot be justified to fulfill the research purpose/objective.

b. Where FH Researchers collect personal information from other organizations, these researchers shall obtain assurances from those other institutions that consent or other authority to disclose has been appropriately obtained.

3.8 Limiting Use and Disclosure

a. Disclosure for Recruitment

The disclosure of individuals' identities for the purpose of contact to invite participation into a research study (i.e. research recruitment) is prohibited. Without prior consent-to-contact, researchers shall not obtain data from care providers for this purpose. FH Researchers shall not obtain the names of the potential research subjects from other public bodies or from patient care providers at FH without pre-authorized consent to contact. Consent authority belongs to the individual only.

b. Release of Tissue

(i) The release of an entire tissue sample, originally obtained for purposes related to the provision of medical care, is prohibited unless consent for its use for research is obtained. This also applies to the tissue of deceased individuals because family members may require access to the tissue for future genetic testing or other purposes related to their health.

(ii) The release of tissue that has been specifically consented to for the purpose of the research or for which there is a waiver of consent shall be controlled by the applicable guidelines of FH Anatomical Pathology.

c. Personal information shall be used and disclosed only on a need-to-know basis.

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c. Transfer Outside of Canada

Explicit informed consent describing the nature of the disclosure shall be obtained as per requirements under the B.C. Freedom of Information and Protection of Privacy Act if the personal information is to be transferred out of Canada as no disclosure outside of Canada of identifiable data is permitted without the consent of the individual/research subject.

d. FH data stewards, or research staff under the direction of a FH **PI** principal investigator, shall only disclose or release identifiable personal information for research purposes, to which they have access, if consent has been given or a waiver of consent has been obtained from the FH REB, if its release meets applicable sections of the FOIPPA and of the specific protocol approved by the FH Research Ethics Board and/or is required through subpoena, court order or legislation.

3.9 Retention

Data shall be retained only as long as needed to fulfill its research purpose and in accordance with any applicable regulatory requirements. Data shall be retained and stored in a fashion that preserves its confidentiality, integrity and availability.

3.10 Accuracy

Data accuracy shall be supported in order than quality is maintained.

3.11 Confidentiality Safeguards

a. Personally identifiable data shall be de-identified (made non-identifiable) or rendered anonymous to an appropriate degree before any disclosure or use is made of data collected for research purposes. Exceptions, in which personally identifiable information is collected, used or released, shall be approved by the FH Research Ethics Board and the appropriate confidentiality protections applied.

b. Where identifiable information is required in order to link records from different systems, such linkage shall be done in a secure fashion, with limited access to the identifiers, and identifiers shall be removed at the first possible opportunity. Such secure and controlled linkage of FH data with other FH data, or with external data shall either be undertaken by FH or by a trusted third party such as the Ministry of Health or the Center for Health Services and Policy Research.

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c. Any third party, such as collaborating researchers or sponsoring companies, with whom research results are shared, shall agree to maintain confidentiality as a condition of the contract/clinical trial agreement for that research study in accordance with the requirements of the FOIPP Act.

d. All FH researchers and research staff shall maintain confidentiality of information, learned during the course of the research, even after their work relationship with FH ends.

3.12 Security Safeguards

a. Protecting Confidentiality, Integrity and Availability

Security controls shall be applied to personal information in the custody of a FH researcher to ensure that what has been established as an appropriate activity is undertaken responsibly and to protect personal information collected for research purposes from unauthorized access, collection, use, disclosure or disposal.

b. Destruction

When data is no longer needed, it shall be securely erased or rendered anonymous so that destruction processes occasion no breaches of confidentiality or organizational security.

3.13 Individual Access

Individuals shall be allowed a right of access to their own identifiable information via standard FH Release of Information policy and procedures, **through the FH Research Office.**

3.14 Openness

FH Research shall make readily available to individuals specific information about its policies and practices relating to the management of personal information for research purposes.

3.15 Challenging Compliance

FH shall enable an individual to exercise their right to challenge FH's compliance with privacy legislation and shall respond to any inquiries from individuals concerning the collection, use and disclosure of their personal information for research activities by conducting an appropriate investigation. Any research

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subject, research subject's partner/family member or member of the public can lodge a query or complaint with any FH staff.

3.16 Breach of Privacy and Confidentiality

(i) Breaches of an individual's privacy and confidentiality which shall be considered a violation of this policy can include, but may not be limited to:

1. unapproved access to personal information in the custody of FH; specifically the disclosure of individuals' identities for the purpose of contact to invite participation into a research study (i.e. research recruitment) is prohibited without a written signed consent-to-contact by the individual;
2. the indiscriminate release of personal information with or without consent that does not meet the previously defined and approved purposes of the research study, and;
3. the use or disclosure of personal information by the FH Researcher for purposes other those approved by the FH REB.

(ii) Violations of this policy are subject to FH investigation and serious consequences, including dismissal.

4. PROCEDURES

Procedures may be amended without further approval by the Vice President Academic Development and Clinical Innovation provided the new procedures conform to the approved policy.

4.1 Accountability And Obligations

To ensure that the obligations of FH are discharged in such a way that the privacy and confidentiality rights of individuals whose personal information may be used for research purposes, the following institutional and individual responsibilities are established and recognized.

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4.1.1 FRASER HEALTH⁵

a. Research requiring the collection, use and/or disclosure of personal information shall be conducted according to the requirements of the FOIPP Act, the 'Tri-council Policy Statement: Ethical Conduct for Research Involving Humans' , the CIHR "Best Practices Protecting Privacy in Health Research" for sharing and protecting personal information and require the approval of the FH Research Ethics Board.

b. FH shall ensure that individuals covered by this Policy receive adequate training and supervision so that they have a clear understanding of their role and responsibility as it relates to the maintenance of privacy and confidentiality of personal information in addition to access and use. A collaborative relationship is in place between FH Research and FH Information Management so that education and awareness regarding privacy and research will be included in educational material for FH personnel.

c. FH shall review information collection and handling practices to ensure compliance with this Policy and its procedures on an annual basis, including access and audit policies and practices of oversight bodies such as Health Canada, or research funding organizations.

d. FH shall implement a process to ensure that complaints/concerns from an individual regarding the use of their personal information are handled appropriately.

4.1.2 THE FH RESEARCH ETHICS BOARD

a. The FH REB shall comply with the requirements of the FH policy on "*The Ethical Conduct of Research and Other Studies Involving Human Subjects*" in order to ensure that appropriate consent shall be obtained or if otherwise, shall document the reasons for providing a waiver of consent, that the stated purposes correlate with the information specified in the research protocol, that confidentiality safeguards shall be put into place for the collection and disclosure of any identifiable information, and that consent-to-contact is obtained for recruitment purposes.

⁵ Fraser Health is represented by the responsible Executive, the Vice President Academic Development and Clinical Innovation and the FH Research Administration and Development Office. The individual designated as the Head of the Public Body is responsible specifically for requirements of the FOIPP Act.

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4.1.3 THE FH DEPARTMENT/UNIT

a. Access to and the release of personal information, including tissue, to FH Researchers under the custody of FH shall be controlled by the designated FH [Steward](#) for Information Management, Decision Support and Anatomical Pathology and any other designated information steward.

b. FH stewards shall document specifications and procedures that comply with this policy and that are applicable to their department/unit and the type of information held by that department/unit. At a minimum, the documentation should include standards for the mechanism by which information is released, for the de-identification of information released to FH Researchers, for the application of other appropriate confidentiality and security provisions and requirements for the retention, destruction or return of the information upon completion of the research study.

4.1.4 THE FH ADMINISTRATIVE SUPERVISOR FOR THE RESEARCHER

a. The Administrative Supervisor (e.g. Department/Division Head/Manager) for the FH Researcher shall ensure that those who conduct, and those who are being trained to conduct, such research understand their responsibilities for maintaining the privacy and confidentiality of the research subjects and that they receive appropriate training in this regard. This type of training includes promoting an awareness of privacy policies and other relevant standards (e.g., legal, professional and institutional).

4.1.5 THE FH RESEARCHER

a. The FH researcher shall detail accurately and completely the research purposes to which personal information is required in the study protocol, the FH Application for Initial Ethical Review and study consent form or if a waiver of consent is required, the reasons why obtaining consent is impossible [i.e. not impractical or inconvenient].

b. The approval of the FH REB and the FH letter of "[Authorization](#) to Conduct Research" must be obtained by the FH Researcher and provided to the department/unit's data steward before access to personal information can be given by that department/unit.

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c. The FH researcher who requires access to personal information under the custody of FH shall complete and sign the FH [Data Access Agreement](#) or other applicable department letter of confidentiality in order to obtain the release of this information. Refer to Section 4.2.2 [Specific Procedures](#).

d. For research requiring consent, the FH researcher shall obtain the written signed consent of the research subject /legally authorized representative for the collection, use and disclosure of any of their personal information for research purposes.

e. The FH researcher shall ensure that procedures for revoking consent are specified in the consent form for all research studies.

f. The FH researcher shall maintain and make available all relevant records including consent forms and revocation documents as required by FH and applicable oversight bodies or as required by law.

4.2 SPECIFIC PROCEDURES

4.2.1 Obtaining Consent to Contact

The FH "Consent-to-Contact For Research Form" shall be used by any FH researchers who may be interested in recruiting subjects for future research.

The consent-to-contact form does not require FH REB approval, but must be included with any initial application of ethical approval for any specific study wherein that form would/will be used.

4.2.2 Obtaining Access to FH Personal Information

a. A consistent process shall be developed for access to physical charts, electronic records and other clinical information, i.e. tissue, whether that access is through the Health Records Department, Decision Support or other departments, such as Anatomical Pathology or Communicable Disease Units. Access to personal information shall follow a consistent process across the Health Authority as under the direction of the FH steward for personal information.

b. Authority to release personal information of any kind is contingent upon the FH Research Office issuing the FH letter of "[Authorization](#) to Conduct Research". This

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letter signifies that the appropriate approvals have been obtained by the FH Researcher and that the initiation of any research-related procedures including the release of personal information can commence. The FH Researcher must provide a copy of this signed letter to the department holding the required information.

The required approvals include:

- FH Research Ethics Board Certificate Of Initial Approval
- FH Department Agreement For Providing Research-related Services [**DAR** Form*]
- For clinical trials: Health Canada Letter of No Objection
- For industry sponsored clinical trials: executed Clinical Trial Agreement.

***DAR:** Note that the FH Researcher must have obtained agreement from FH departments/units holding personal information that the release of personal information can be carried out by that department/unit and that the estimated cost of performing the service has agreed to by that department/unit if the study is funded. Refer to the FH Policy on "FH Research" for further details regarding this requirement.

c. The data steward for that department/unit shall provide the FH Researcher with the FH Data Access Agreement Form or other applicable department letter of confidentiality understanding for signature.

d. The FH Researcher must sign the Data Access Agreement/confidentiality understanding before the personal information shall be released by the data steward to the FH Researcher.

e. The FH Department/unit must retain a copy of the FH Researcher's signed and dated Data Access Agreement/letter of confidentiality on file.

4.2.3 Managing Consent-to-contact and Consent Records

All research records, specifically electronic data holdings, wherever possible should be designed to include a consent-to-research or a consent-to-contact field.

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4.2.4 Revoking Consent

a. If consent is revoked a status flag shall be set to 'deactivate' the research subject's information. When that occurs the research subject's information shall no longer be used for research. All personal information shall be inaccessible to new studies but shall be kept as per retention guidelines to support the integrity of previous studies and/or to provide an audit trail for clinical trials research if applicable. Any derived results are maintained as necessary.

4.2.5 Storage of Identifiable Personal Information

- a. Identifiable personal information can be stored on mobile devices or laptops only if encrypted.
- b. Identifiable personal information should not be stored on C Drives unless appropriately protected and backed up as per FH Information Security standards.

4.2.6 Complaints

- a. This information is available on request in hard copy which can be obtained by contacting the FH Director, Research.
- b. Any individual or legally authorized representative who has concerns about the collection, use and disclosure of their personal information for research related purposes may contact the FH Research Ethics Board, the FH Director, Research, the Vice President Academic Development and Clinical Innovation or any other FH staff, or the Office of the B.C. Privacy Commissioner.
- b. The query/complaint shall be brought to the attention of the Director, Research who will establish a process for reviewing and investigating complaints under the direction of the Vice President Academic Development and Clinical Innovation.
- c. A documented process to track the status/outcome of complaints shall be put in place.
- d. A reporting mechanism shall be in place to maintain records of all complaints and queries.

5. DEFINITIONS

Access

The ability to have, see, view, read or take copies of data.

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'Authorization to Conduct Research' Letter

- Letter issued by the FH Research Office signifying that the appropriate approvals applicable to the named study have been obtained. These approvals include:
- FH Research Ethics Board Certificate of Initial Approval
- FH Department Agreement For Providing Research-related Services – if services are required
- For clinical trials: Health Canada Letter of No Objection
- For industry sponsored clinical trials: Executed Clinical Trial Agreement

Confidentiality

The responsibility to maintain data to which the organization or individual has established the authority to collect and use, in a fashion protected from inappropriate access and use.

Co-investigator

A co-investigator is anyone other than the principal investigator who is deemed by the principal investigator to carry out this role and who has some responsibility for the conduct of the trial.

Consent

Informed consent is the agreement of a subject/legal representative to take part in research after the procedures, costs, and potential risk and benefits have been explained in a manner that the subject can understand. The written informed consent of subjects to participate in a research study is given voluntarily based upon a thorough consent process and may be withdrawn at any time, for any reason, and by any communication means. Consent signifies that the subject has made a decision to actively 'opt-in' to a research study. The consent of the subjects must be documented, if obtained by other non-written means.

Control

The responsibility to maintain stewardship when data is not physically held by the organization.

Custody

Refers to the physical holding of data.

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Data Access Agreement [DAA]

A DAA sets out conditions under which data, including tissue, may be used and managed over its lifetime. The conditions are applied to the use, linkage, and subsequent re-identification (if possible), protection, destruction, archiving, or return of such data as appropriate to the level of identifiability of the data, the sensitivity of the data and any other criteria which FH may wish to consider.

Data Linkage

Data linkage is used to create a new data set by combining other data sets. Such a data set has more detail and more information about an individual and therefore has more value and more concomitant privacy risk.

Directly Identifiable

Identifiable information can identify a specific individual directly. This may occur even without the subject's name when the existence of other variables (i.e. other categories of information) makes the information easy to tie to an individual.

Disclosure

The act of providing data collected for one purpose to any individual or organization either of a different, or a *consistent* purpose. Typically disclosure for patient care is done under the *consistent purpose principle* whether inside or external to the organization. Where data is disclosed inside the organization from one department to another, for a different purpose the test of consistency must be actively applied. Research is not considered a *consistent purpose* where data was collected for patient care.

FH Researcher

A researcher who must apply for ethical review and approval by the FH REB is anyone who carries out research at FH as described under Section 3.2 of the FH Policy "The Ethical Conduct of Research-related Activities Involving Human Subjects".

- the research is under the direction of, conducted by, or involves any FH employee or agent [e.g. any physician with privileges at FH] using any FH property or facility, or;
- the research is under the direction of, conducted by, or involves any FH employee or agent [e.g. any physician with privileges] in connection with his

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or her FH responsibilities, such that the research may also be conducted outside of the FH jurisdiction.

Identifiers

Examples of identifiers include but are not limited to: name, address, personal health number, medical record number, other hospital or organizational number [e.g. clinical accessioning number], date of birth, MSP codes, postal codes.

Indirectly Identifiable/De-identified

Indirectly identifiable information or de-identified information can be linked to a specific individual by way of an identifying tag or identifier. Usually the key to linking the information to the subject identity is retained by a specified custodian for that information.

The information must not include any of the following identifiers: Name, address, PHN, Medical Record Number, other hospital or organizational number, Date of Birth. MSP codes, PHNs. Age is provided using standard Statistics Canada 5 year age groups, geographic location provided in Health Authority, or Health Service Delivery area designation. Aggregate data is also considered to be de-identified.

Unique codes (either single or double, numeric and/or alpha combination) can be used as unique identifiers. They should not include any of the identifiers listed above.

Legally Authorized Representatives

The person who can sign on behalf of the subject in the event that the subject is deceased, deemed to be incompetent by virtue of age or certified mental incompetence.

Non-identifiable/Anonymous/Anonymized

Anonymized data/tissue was originally identified but has been permanently stripped of all possible identifiers and therefore is no longer identifiable. Anonymous data or tissue is anonymous due either to the absence of tags or records [i.e. the source has never been identifiable]. This means that no member of the research group knows the subject identity and that identification of subjects is NOT possible by any means or by the information obtained from subjects.

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Personal Information

Personal information is defined by FOIPPA as any recorded information about an identifiable individual other than contact information. Information can be in paper, electronic or photographic form, or as tissue⁶ about which can reasonably be said to identify an individual.

Examples of personal information include, but are not limited to:

- name, address, or telephone number [business contact information is not included],
- race, national or ethnic origin, colour or religious beliefs or associations,
- age, sex, sexual orientation, marital status or family status,
- an identifying number, symbol or other particular assigned to the individual, such as date of birth, PHN, MRN or any organizational and/or department number such as lab number or surgical number,
- fingerprints, blood type or inheritable characteristics,
- health care history including information about disabilities, medications [e.g. from Pharmacare databases], tissue [including blood and DNA], outcome data from Provincial registries,
- education, financial, criminal or employment history,
- anyone else's [recorded] opinions about the individual,
- the individual's [recorded] personal views or opinions except if they are about someone else.
- tissue [living and dead, including blood and DNA] which has been collected for any purpose, including wet tissue, frozen tissue, paraffin blocks including tissue and slides with tissue.

Personal Information Management Practices

The organization's policies and procedures, both written and unwritten by which it collects, uses, stores, retains, protects, discloses and destroys data, collected by any staff member for any purpose.

Principal Investigator

The principal investigator is the FH researcher who is deemed to have overall accountability for the research conducted at a FH site.

⁶ Source: Office of the B.C. Privacy Commissioner, June 2005

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External Researchers may be the principal investigator for a REB approved study at another site.

Privacy (Information Privacy)

The right of an individual to exercise control over their data, its use and is disclosure.

Registries

In the absence of a more official and specific definition a '*Registry*' may be considered any data holding that is maintained over time to track individuals, often aligned to a specific disease. Data purposes/data uses for Registries must be defined so that privacy protection can be applied in alignment with privacy principles and legislation.

Research

Source: FH Policy on "The Ethical Conduct of Research and Research-related Activities Involving Human Subjects"

Research involving human subjects is defined as any systematic investigation (including pilot studies, exploratory studies, and academic course work assignments) designed to contribute to generalizable knowledge. Generalizable knowledge consists of facts, theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. Research includes:

- obtaining data about a living individual through intervention (e.g. a medical procedure) or interaction (e.g. an interview) with the individual, or the obtaining of private personal information about the individual;
- secondary use of data (e.g. information, such as medical records, collected for purposes other than the proposed research) that contains identifying information about a living individual, or data linkage through which living individuals may become identifiable;
- naturalistic observation, except the observation of individuals in contexts in which it can be expected that the participants are seeking public visibility;
- the use of human remains, cadavers, tissues, biological fluids, embryos or fetuses.

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Retention

The act of keeping or storing data. Retention policies and retention cycles must be applied so that data is retained to make appropriate decisions and for a sufficient period that an individual may challenge decisions based on the data.

Security

Security includes the act of safeguarding data. Security controls can include a wide range of protections including physical security, electronic security and access controls.

Steward

Data stewards manage data holdings in compliance with the FOIPP Act as well as industry standards and best practices and are responsible for its appropriate Collection, Use and Disclosure. Fraser Health is responsible for setting policy in respect of data stewardship.

Subject

A subject is a person about who a research investigation is being conducted for a purpose other than the sole purpose of benefiting the subject as an individual, specifically that of the discovery of new knowledge. If a person, such as a family member or employer is asked to provide information about another individual, then both individuals are considered to be subjects. Donors of organs, tissues, and body fluids for research purposes and individuals, whose records are used for research, are considered to be subjects.

6. REFERENCES

1. Audit

FH Policy on "Audit of Electronic Health Information Access"

Refer to:

<http://fhaweb/NR/rdonlyres/ehtrtv7etrfzhpvmz33fyzl6rnlpbybmeywdx7e6343wgqyailznrqwp2m2kur4la2t5whfufk2qm/Audit%2bof%2bElectronic%2bHealth%2bInformation%2bAccess%2b-%2bAp.pdf>

2. CSA Model Code Principle #2: Identifying Purposes

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3. CIHR

Best Practices for Protecting Privacy in Health Research” (2004).

4. CSPI

FH Policy “Confidentiality and Security of Personal Information”

Refer to:

<http://fhaweb/NR/ronlyres/ezlnb4uhxxhmoqr6vvwkrzmvwi25jegxi2d5akht5fzmfq3vbaw2dtbrgogllly3jgkvpqk4fbmntn/Confidentiality%2band%2bSecurity%2bof%2bPersonal%2blnformati.pdf>

5. ETHICS

FH Policy on “The Ethical Conduct of Research and Other Studies Involving Human Subjects”

Refer to:

<http://fhaweb/NR/ronlyres/eweebdocxykv4psfr3yrbmbkzctlcjzq4nw6d2jxizndpd3cchunpymokil24wk72ockiuahpmwvfh/Ethical%2bConduct%2bof%2bResearch%2band%2bOther%2bStudies%2blnvo.pdf>

6. FOIPPA

BC Freedom of Information and Protection of Privacy Act – Section 32, 33, 34 and 35

Refer to:

http://www.qp.gov.bc.ca/statreg/stat/F/96165_01.htm#section35 and http://www.qp.gov.bc.ca/statreg/stat/F/96165_01.htm#part1

As a public body, the FH, and the FH REB and researchers under its jurisdiction are obliged to meet the legislative requirements of the *Freedom of Information and Protection of Privacy Act*, specifically S. 35. *Disclosure for Research or Statistical Purposes*.

Section 35 stipulates that consent must be obtained unless it is impracticable (not simply inconvenient) to do so and the Privacy Commissioner or a Research Ethics Board has waived the consent requirement. Under BC Law if identifiable data is obtained under a waiver of consent the information must not be used to contact the individuals.

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7. TCPS

The 'Tri-council Policy Statement: Ethical Conduct for Research Involving Humans' provides the Canadian framework for ethical review of research involving human subjects.

Refer to:

<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

TCPS Article 2.1 (c)

The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

The research involves no more than minimal risk to the subjects;

The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;

The research could not practicably be carried out without the waiver or alteration; Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and

The waived or altered consent does not involve a therapeutic intervention.

TCPS Article 3.3

If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:

Identifying information is essential to the research; and

They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects;

Individuals to whom the data refer have not objected to secondary use.

The informed consent of those who contributed data or of authorized third parties; or

An appropriate strategy for informing the subjects; or

Consultation with representatives of those who contributed data.

Article 3.4 is based on the concept of a proportionate approach to ethical assessment of research. Under it, the REB should focus on projects above minimal risk, or modulate requirements and protection proportionate to the magnitude and

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probability of harms, including the likelihood that published data can be linked to individuals. In highly sensitive situations such as when identifiable data will be published or other instances when there is a significant risk of breach of confidentiality, Article 3.4(a) indicates that such deliberations and balancing may lead the REB to seek consent to use the stored data from those who made the contribution.

It may be impossible, difficult or economically unfeasible to contact all subjects in a study group to obtain informed consent. This can occur when the group is large or its members are deceased, geographically dispersed or difficult to track. In such cases, Article 3.4(b) requires that the researcher propose an appropriate strategy for informing the relevant parties or, in accord with Article 3.4(c), that there be consultation with representative members of the affected group (e.g., in an AIDS study, contacting one or a number of AIDS advocacy groups), or that there be some way to sample the opinions of a subset of individuals in the group.

8. FH POLICIES

“FH Research” [Approved June 21, 2005]

“The Ethical Conduct of Research and Other Studies Involving Human Subjects”
[Approved April 12, 2005]