

		Page 1 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

DATE(S) REVISED / REVIEWED SUMMARY ¹

Version	Date	Comments / Changes
1.0	June 2005	Initial Policy
2.0	March 2014	Format; links updated.
2.0	March 2014	Policy Article 1.0 - Deleted "provision of tissue samples that are required specifically for experimental manipulation for future possible research, e.g. stem cell research" as this was redundant; deleted "procedures related to the use of specialized equipment, [e.g. imaging]" as this was redundant and deleted "modifications to existing information systems or implementation of new systems [e.g. databases]", as this would not occur.
2.0	March 2014	Policy Article 1.1 - Deleted reference to specific FHA policies as all FHA research related policies are included in the Reference section.
2.0	March 2014	Policy Article 2.1 - Replaced "Legal Representative" with "Substitute Decision Maker".
2.0	March 2014	Policy Article 3.1 - Deleted "use of specialized equipment, and;" any other service requested of an External Researcher
2.0	March 2014	Policy Article 3.4 a (i) - Replaced "Information Management, Decision Support" with "Health Records, Health and Business Analytics"
2.0	March 2014	Policy Article 3.4 a (c) - Replaced "Legal Representative" with "Substitute Decision Maker".
2.0	March 2014	Policy Article 3.4 d - Deleted such as the Ministry of Health or the Center for Health Services and Policy Research [CHSPR].
2.0	March 2014	Policy Article 4.1.2 a - Replaced "Legal Representative" with "Substitute Decision Maker".

¹ © Fraser Health Authority



		Page 2 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE
		March 2014

INTENT / PURPOSE

Specific Fraser Health Authority² [FHA] programs/services may be asked by researchers not affiliated with FHA [i.e. <u>External Researchers</u>] to provide <u>services</u> related to specific research projects. These services may include, but are not necessarily limited to:

- provision of diagnostic tests that External Researchers are unable to provide themselves;
- access to <u>Personal Information</u>, (which may include provision of tissue samples)
 originally collected for purposes related to the provision of care [i.e. not research], in
 order to collect data about a FHA patient, client or resident who has consented to
 participate in a specific research study approved by a non-FHA Research Ethics Board
 for a non-FHA institution;
- access to facilities to post, place and/or distribute materials advertising research studies which require access to prospective research subjects.

The purpose of this policy is to ensure that due diligence is exercised by FHA programs/services when making a determination to provide research-related services to researchers not directly affiliated with FH.

1.1 Compliance with B.C. Privacy Legislation and Applicable Polices

As a public body, FH is a <u>steward</u> of personal information and therefore accountable for the protection of the <u>privacy</u> and <u>confidentiality</u> of all <u>personal information</u> 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 or collected indirectly from other care providers and institutions during the provision of care at FH.

British Columbia's *The Freedom of Information and Protection of Privacy Act* **FOIPPA** provides a framework for managing the circumstances under which personal information may be collected, used or disclosed 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 2, 2010) and

² The Fraser Health Authority will be denoted as Fraser Health [FH] throughout this document.



		Page 3 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

the Canadian Institute for Health Research "Best Practices for Protecting Privacy in Health Research" (CIHR, 2005).

1.2 Definition of Personal Information

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

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

- name, address, or telephone number [place of 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, surgical number, clinical accessioning number for tissue.
- fingerprints, blood type or inheritable characteristics,
- health care history including, but not limited to, 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,
- <u>tissue</u> [living and dead, including blood and DNA] which has been collected for any purpose, including wet tissue, frozen tissue, paraffin blocks containing tissue and slides with tissue.

POLICY

FHA understands that personal information and services under its control may provide valuable data and resources to researchers outside of FHA. FHA recognizes, however, that it has a responsibility to ensure that meeting FHA service delivery requirements is always the first



		Page 4 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

priority and that accordingly, it is the right of any FHA program/service to decide whether it has the resources to accommodate the External Researcher's request for research-related services.

In addition, FHA is committed to protecting individual privacy rights. FHA 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 collection, use, disclosure, access and retention of information about them. The right of privacy is exercised by providing <u>consent</u>.

FHA believes that the protection of personal information is a fundamental and integral part of every research process and therefore is committed to ensuring that confidentiality is maintained through the implementation of responsible personal information management <u>PIM</u> and <u>security</u> practices.

2.1 Statement of Privacy and Confidentiality Principles

- 2.1 Voluntary and informed <u>consent</u> from legally competent individuals or their <u>substitute decision makers</u> 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 data in the manner defined in the consent form.
- 2.2 Consent for use of information for secondary purposes is obtained to ensure that individuals agree that the data/tissue they provided for their *Care* can also be used for *Research*. Consent of the individual for the use of this type of data/tissue for research establishes the right to use data/tissue collected for *Care* for the secondary purpose of *Research*.
- 2.3 Access to identifiable personal data for research without consent shall be subject to specific legal requirements under the FOIPPA and the approval of the institutional REB for that consent waiver
- 2.3 The confidentiality of secondary sources of information must also be protected when used for research purposes.
- 2.4 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



		Page 5 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

frivolous information. Collection of unnecessary information constitutes a breach of the collection principle and potentially a risk to the individual.

- 2.5 The use of personal information should adhere to the principle of maximum anonymity with minimum disclosure to protect the confidentiality of the research subject.
- 2.6 All paper documents, electronic storage media containing personal information and collections of tissue used for research purposes are the property of FH but the information/tissue belongs to the person about whom the information/tissue refers.

3.1 Scope

This policy applies to the provision of services by FHA staff to External Researchers related to the following:

- 1. access to any personal information for which FHA is considered the data <u>Steward</u>, including information contained in paper records, electronic databases and data warehouses, or tissue repositories and the personal information of someone for whom there is a legally authorized representative;
- 2. provision of diagnostic services to an External Researcher for their research which has been approved by their institutional REB and for which there is subject consent;
- 3. access to facilities for the placement, posting and/or distribution of research recruitment materials.

3.2. Criteria for Providing Research-related Services

- a. Before FHA programs/services are permitted to provide research-related services to External Researchers, <u>all</u> of the following criteria must be met:
- 1) the research study protocol has received the approval of the Research Ethics Board [REB] for that External Researcher's institution;
- 2) the REB approval includes the written signed consent of the individual subject/substitute decision maker OR REB waiver of consent for that study and as applicable, the approval of other relevant research documentation, i.e. recruitment materials;
- 3) the request for personal information and/or other service provision is congruent with the information specified in either the REB approved protocol and/or informed consent document.



		Page 6 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

- 4) the request for personal information includes the signed consent form of the specific individual.
- 5) the service can be provided without interrupting the mandated operations of a department/unit;
- 6) the service can be provided on a cost recovery basis, and;
- 7) appropriate procedures for ensuring confidentiality can be implemented by the program/service providing access to personal information.

3.3 Program/Service Provision Requirements

- a. Each program/service providing services shall document and make available their requirements for the provision of the applicable service, including an applicable cost recovery schedule. Refer to **Procedure 4.1.2**.
- b. An annual report of the research-related services provided by the department/unit to External researchers shall be made to the FHA Research and Evaluation Services Department.

3.4 Provision of Personal Information

a. Control By FH Stewards

- (i) Access to and the release of personal information, including tissue, to External Researchers under the custody of FHA shall be controlled by the designated FHA <u>Steward</u> for Health Records, Health and Business Analytics and Anatomical Pathology and any other designated information steward.
- (ii) FHA stewards shall document specifications and procedures that comply with this policy and that are applicable to their program/service and the type of information held by that program/service. At a minimum, the documentation should include standards for the mechanism by which information is released, for the de-identification of information released for External Research purposes, 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.
- (iii) FHA stewards shall have the responsibility to challenge the requests of External Researcher's for release of any personal information if there is uncertainty about whether any of the requirements defined under Section 3.2 <u>Criteria</u> can be met.



		Page 7 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

b. Release of Tissue

- (i) 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.
- (ii) The release of an entire tissue sample, originally obtained for purposes related to the provision of medical care, is prohibited unless consent for its entire 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.
- (iv) 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 FHA Anatomical Pathology.

c. De-identification

(i) Unless there is a mechanism that allows the personally identifiable information to be <u>de-identified</u> to an appropriate degree or <u>anonymized</u> before any disclosure or release is made to External researchers, the use of the personally identifiable information shall be approved by the REB of the External researcher's institution, have evidence of written signed consent form the identified individual/substitute decision-maker or a REB waiver of consent.

d. Data Linkage

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 FHA data with other FHA data, or with external data shall either be undertaken by FHA or by a trusted third party.

e. 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:



		Page 8 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION	DATE APPROVED	CURRENT VERSION
Vice President, Medicine June 2005		<u>DATE</u>
		March 2014

- 1. Unapproved access to personal information in the custody of FHA; 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 External Researcher for purposes other than the approved purposes.
- (ii) Violations of this policy are subject to FHA investigation and serious consequences, including dismissal.

DEFINITIONS

Confidentiality

Confidentiality is the restriction of information that identifies a subject outside of the research group itself. In this case, the subject can be identified by the use of a unique study code which relates the data collected about the subject to the subject. Confidentiality is maintained if only 'coded' information is sent outside of the research group.

Consent

<u>Informed</u> 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.

Custody

Refers to the physical holding of data.

Data Access Agreement [DAA]



		Page 9 of 19
POLICY TITLE		<u>NUMBER</u>
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

The DAA sets out conditions under which the data will be used and managed over its lifetime. The conditions which will be applied to the use, linkage, and subsequent re-identification (if possible), protection, destruction, archiving, or return of such data will be appropriate to the level of identifiability of the data, the sensitivity of the data and any other criteria which FHA may wish to consider. It also includes requirements for safeguarding information as well as prohibitions on the transfer of identifiable information out of Canada without the consent of the individual.

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.

De-identified/ Indirectly Identifiable

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.

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.

External Researcher

Any researcher who does not have either direct employment status or privileges with FHA or an affiliated FHA status.



		Page 10 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

FHA Researcher

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

Identifiers

Examples of identifiers include: 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.

Substitute Decision Makers

The person who can sign a consent form for research participation 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, including codes for re-linking, and therefore can no longer be attributed to an identifiable individual.

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.

Personal Information

Personal information is defined by FOIPPA as any recorded information about an identifiable individual other than business contact information. Information can be paper, electronic or photographic form, and tissue³, which can reasonably be said to identify an individual.

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

 name, address, or telephone number [place of business contact information is not included],

³ Source: Office of the B.C. Privacy Commissioner, June 2005



		Page 11 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

- 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, surgical number, clinical accessioning number for tissue.
- fingerprints, blood type or inheritable characteristics,
- health care history including, but not limited to, 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
- <u>tissue</u> [living and dead, including blood and DNA] which has been collected for any purpose, including wet tissue, frozen tissue, paraffin blocks containing 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 FHA Researcher who is deemed to have overall accountability for the research conducted at a FHA site.

Privacy

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



		Page 12 of 19
POLICY TITLE		<u>NUMBER</u>
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

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 foetuses.

Secondary Sources of Personal Information

Secondary sources of personal information include any information that was originally collected for a purpose other than research, i.e. care, and is retained within the custody of the steward [e.g. FHA] for that information.



		Page 13 of 19
POLICY TITLE		<u>NUMBER</u>
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

Security

Security controls can include a wide range of protections including physical security, electronic security and access controls.

Services

FHA departments/units that can either carry out a specific procedure, e.g. providing personal information, e.g. health records/tissue, to a non FHA-affiliated researcher, i.e. External, who otherwise does not have that capability.

Steward

Within FHA, individuals charged with the responsibility of maintaining 'custody' of sources of personal information, including tissue, include designated individuals within Health Records, Health and Business Analytics and Anatomical Pathology and other departments as applicable.

Subject

A subject (also known as a research participant) 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.

Tissue

Tissue may be living or dead and includes blood, DNA, and any other tissue.

TCPS Compliant REB

FHA recognizes the TCPS compliant REB's of academic and academic healthcare organizations.



		Page 14 of 19
POLICY TITLE		<u>NUMBER</u>
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

PROCEDURE

4.1 Accountability and Obligations

To ensure that the obligations of FHA are discharged in such a way that the commitment to patient care and the privacy and confidentiality rights of individuals whose personal information might be used for research purposes, the following institutional responsibilities are established and recognized.

4.1.1 FRASER HEALTH

- a. All personal information for research purposes shall be disclosed under the requirements of the B.C. "Freedom of Information and Protection of Privacy Act" FOIPPA and the "Tri-council Policy Statement: Ethical Conduct of Research Involving Human Subjects" TCPS 2, 2010.
- b. FHA will make available learning opportunities to the individuals covered by this Policy to ensure 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.
- c. The FHA Director, Evaluation and Research Services shall oversee an annual review process to ensure that compliance with this Policy is maintained.
- d. The FHA Director, Evaluation and Research Services shall implement a process to ensure that complaints/concerns from an individual regarding the use of their personal information are handled appropriately. Refer to Section 4.2 **General Procedures**.

4.1.2 PROGRAMS/SERVICES

a. Consistent Process

A consistent process shall be developed for access to <u>physical charts</u>, <u>electronic records</u> and other <u>clinical information</u>, <u>i.e. tissue</u>, for research purposes whether that access is through the Health Records Department, Health and Business Analytics or other departments, such as Anatomical Pathology or Communicable Disease Units. Access to personal information shall



		Page 15 of 19
POLICY TITLE		<u>NUMBER</u>
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

follow consistent process across the Health Authority as under the direction of the FHA steward for personal information.

b. Evaluating And Approving Requests From External Researchers

FHA programs/services shall implement the following general steps in order to consider and evaluate requests from External researchers to provide research-related services. Individual departments may implement specific requirements as necessary.

(i) Upon receipt of an External Researcher's request, the FHA program/service will provide the External researcher with their⁴ requisition for research related services and cost recovery schedule. This requisition must be completed by the External Researcher in order to have the request considered further by the program/service.

At a minimum the FHA program/service requisition should require External Researcher's name, affiliation, research study title, their institution's REB approval date, study period over which the service is required, details of the service/information/tissue required, whether the information will be transferred outside of Canada, and list the required approval documents.

- (ii) Upon completion by the External Researcher and receipt of the requisition by the program/service, the FHA program/service shall ensure that copies of the following institutional approval documents from the External researcher for that particular research study are provided:
 - The certificate of initial ethical approval from the institutional REB and, if the study, has been ongoing elsewhere, the certificate of annual renewal from the institutional REB.
 - Written assurance from the External Researcher's institution that the REB for that
 institution is Tri-Council compliant. <u>TCPS Compliant</u> (note this may be included on the
 certificate of ethical approval).
 - For the release of patient information: 1) The institutional REB approved consent form OR waiver of consent with research protocol; 2) the ⁵ signed consent of the research subject(s) if consent was obtained. The signed consent sheet must include the study

⁴ The 'requisition' may be any type of form designed by a program/service to solicit information from the External researcher that is required to make this determination.

⁵ Note that it is acceptable to obtain the signed consents of the research subjects for release of information including tissue on an ongoing basis as these are often obtained on an ongoing basis and are needed as a reference for the tissue sample required.



		Page 16 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

title that matches the study title on the consent form and the REB certificate of approval, and; 3) the completed and signed Data Access Agreement required by FHA Privacy for the release of any information, and;

- Approved research protocols may be a specific department requirement.
- Waiver of Consent: A waiver of consent for the secondary use of information that identifies an individual may be issued by an institutional REB for a particular study. If this is the case, a signed letter from the institutional REB must be obtained as evidence that the waiver has been granted for the study identified on the REB certificate of approval. The waiver must comply with the TCPS 2 waiver of consent requirements.

Transfer of Information Outside of Canada

No disclosure outside of Canada of identifiable data is permitted, under FOIPPA, without the explicit written consent of the research subject/substitute decision maker. The consent form must state that the personal information collected and used for the research study will be transferred outside of Canada if this is the case. If a consent waiver has been approved, FHA Privacy must approve the transfer of the information.

Adjudication

Concerns about the validity of the request and the documents provided should be brought to the attention of the Director, Evaluation and Research Services for review.

- (iii) Evaluate whether the request meets the Criteria specified in Section 3.2 of this Policy.
- (iv) Provide written documentation to the External Researchers of the decision to provide or not provide the requested service.

(v) For Release of Personal Information

• The FHA program/service shall <u>de-identify</u> or <u>anonymize</u> the requested information as per their standard procedures before release to the External Researcher.



		Page 17 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

- If the External Researcher has specified that identifiable information is required, the FHA program/service must ensure that the consent form or a waiver of consent for that research study permits the release of identifiable information.
- Ensure that the External researcher signs and dates a copy of the FHA <u>Data Access</u>
 <u>Agreement</u> or other applicable department letter of confidentiality that stipulates how
 the External Researchers will maintain the confidentiality of the information and the
 requirements for the disposal of the information once the study is completed.
- Retain a copy of the External Researcher's signed and dated Data Access Agreement/letter of confidentiality on file.
- (vi) **For All Services:** Require signed confirmation from the External Researcher that reimbursement for the services provided will be provided by the External Researcher and retain a copy of the document on file.

c. Terminating Release of Personal Information

- (i) Research subjects may at any time request that their consent for release of personal information related to a study(ies) be revoked at any time. Should this occur, the External researcher is responsible for notifying the FHA program/service of the revocation.
- (ii) When consent is revoked, the FHA program/service shall set a status flag to 'deactivate' the release of the research subject's information which shall no longer be accessible. When that occurs the research subject's information shall no longer be used for research related to that study.

4.2 General Procedures

a. Investigation of Complaints

i. Individuals who have concerns about the disclosure of their personal information for research related purposes may contact the FHA Director, Evaluation and Research Services, the Vice President Medicine or any other FHA staff, or the B.C. Privacy Commissioner's Office. Research policies and procedures shall be available on request by contacting the Director, Evaluation and Research Services.



		Page 18 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

- ii. Queries/complaints shall be brought to the attention of the Director, Evaluation and Research Services who shall investigate and respond to the person bringing forward the complaint, under the direction of the Vice-President, Medicine.
- iii. The complaint, investigation, outcome and response to the person bringing forward the complaint will be documented and retained on file by the Director, Evaluation and Research Services.

REFERENCES

1. CIHR

Canadian Institutes for Health Research Best Practices for Protecting Privacy in Health Research Refer to:

http://www.cihr-http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf

2. BC Freedom of Information and Protection of Privacy Act – Section 32, 33, 34 and 35 Refer to:

http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96165_03 and http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96165_00

3. TCPS 2 (2010)

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/eng/policy-politique/initiatives/tcps2-eptc2/Default/



		Page 19 of 19
POLICY TITLE		NUMBER
THE PROVISION OF RESEARCH RELATED SERVICES TO NON-FRASER HEALTH RESEARCHERS		TBA
AUTHORIZATION Vice President, Medicine	DATE APPROVED June 2005	CURRENT VERSION DATE March 2014

4. FHA CORPORATE RESEARCH-RELATED POLICIES

- a. Clarification of Ethical Review Requirements for Studies Involving Quality
 Assurance/Improvement, Program Evaluation, Operational Review and Product Evaluation
- b. Research Policy
- c. The Collection, Use and Disclosure of Personal Information for Research-related Purposes Policy
- d. Research Integrity Policy
- e. Whistleblower Protection
- f. Confidentiality and Security of Personal Information
- g. Conflict of Interest Policy