

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**TABLE OF CONTENTS**

**1. PURPOSE [Purpose](#)**

- 1.1 Compliance with B.C. Privacy Legislation and Applicable Polices [Compliance](#)
- 1.2 Definition of Personal Information [Definition](#)

**2. PHILOSOPHY [Philosophy](#)**

- 2.1 Statement Of Privacy and Confidentiality [Principles](#)

**3. POLICY [Policy](#)**

- 3.1 Scope [Scope](#)
- 3.2 Criteria [Criteria](#)
- 3.3 Department/Unit Service Provision Requirements [Department](#)
- 3.4 Provision of Personal Information [Provision](#)
- a. Control By FH Stewards [Control](#)
- b. Release of Tissue [Release](#)
- c. De-identification [Deidentification](#)
- d. Data Linkage [Data Linkage](#)
- e. Chart Reviews [Chart Reviews](#)
- f. Breach of Privacy and Confidentiality [Breach Privacy](#)

**4. PROCEDURES [Procedures](#)**

- 4.1 Accountability and Obligations [Accountability Obligations](#)

**4.1.1 FRASER HEALTH [FraserHealth](#)**

**4.1.2 DEPARTMENTS/UNITS [FHDepartments](#)**

- a. Consistent Process [ConsistentProcess](#)
- b. Evaluating And Approving Requests From External Researchers [Evaluating](#)
- b. Terminating Release of Personal Information [Terminating](#)

**4.2 General Procedures [General Procedures](#)**

- a. Investigation of Complaints [Investigation Complaints](#)

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**5. DEFINITIONS [Definitions](#)**

Confidentiality [Confidentiality](#)  
 Consent [Consent](#)  
 Custody [Custody](#)  
 Data Access Agreement [DAA] [DataAccessAgreement](#)  
 Data Linkage [Linkage](#)  
 De-identified/Indirectly Identifiable [Deidentified](#)  
 Directly Identifiable [DirectlyIdentifiable](#)  
 External Researcher [ExternalResearcher](#)  
 FH Researcher [FHResearcher](#)  
 Identifiers [Identifiers](#)  
 Legally Authorized Representatives [LegalRep](#)  
 Non-identifiable/Anonymous/Anonymized [Nonidentifiable](#)  
 Personal Information [PersonalInformationFOIPPA](#)  
 Personal Information Management Practices [PIM](#)  
 Principal Investigator [PI](#)  
 Privacy [Privacy](#)  
 Registries [Registries](#)  
 Research [Research](#)  
 Secondary Sources of Personal Information [Secondary](#)  
 Security [Security](#)  
 Services [Services](#)  
 Steward [Steward](#)  
 Subject [Subject](#)  
 Tissue [Tissue](#)  
 TCPS Compliant REB [TCPSCompliant](#)

**6. REFERENCES [References](#)**

Audit of Electronic Health Information [Audit](#)  
 CSA Model Code Principle #2 Identifying Purposes [CSA](#)  
 CIHR [CIHR](#)  
 FH Policy "Confidentiality and Security of Personal Information" [CSPI](#)

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

Ethics [Ethics](#)

B.C. Freedom of Information and Protection of Privacy Act [FOIPPA](#)

Tri-council Policy [TCPS](#)

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

## 1. PURPOSE

Specific Fraser Health<sup>1</sup> [FH] departments/units may be asked by researchers not affiliated with FH [i.e. [External](#) Researchers] to provide [Services](#) 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 [Personal Information](#), originally collected for purposes related to the provision of care [i.e. not research], in order to collect data for analysis;
- provision of [Tissue](#) samples that had been collected previously during a procedure related to care and that are required in order to carry out research on specific patient populations, e.g. cancer patients;
- provision of tissue samples that are required specifically for experimental manipulation for future possible research, e.g. stem cell research;
- access to facilities to post, place and/or distribute materials advertising research studies which require access to prospective research subjects;
- procedures related to the use of specialized equipment, [e.g. imaging].
- modifications to existing information systems or implementation of new systems [e.g. databases].

The purpose of this policy is to ensure that due diligence is exercised by FH departments/units 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 [Steward](#) of personal information and therefore 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 or collected indirectly from other care providers and institutions during the provision of care at FH.

<sup>1</sup> The Fraser Health Authority will be denoted as Fraser Health [FH] throughout this document.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

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](#) (1998) and the Canadian Institute for Health Research "Best Practices for Protecting Privacy in Health Research" [CIHR](#) (2004).

This policy is supported by the FH policies:

- *Privacy and Security of Personal Information* (Approved October 2003) [CSPI](#), and,
- *Audit of Electronic Health Information* (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](#).

**1.2 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 paper, electronic or photographic form, and tissue<sup>2</sup>, 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,

<sup>2</sup> Source: Office of the B.C. Privacy Commissioner, June 2005

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

- 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.
- tissue [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.

**2. PHILOSOPHY**

FH understands that personal information and services under its control may provide valuable data and resources to researchers outside of FH. FH recognizes, however, that it has a responsibility to ensure that meeting FH service delivery requirements is always the first priority and that accordingly, it is the right of any FH department/unit to decide whether it has the resources to accommodate the External Researcher’s request for research-related services.

In addition, FH is committed to protecting individual privacy rights. 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 collection, use, disclosure, access and retention of information about them. The right of privacy is exercised by providing [Consent](#).

FH 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 [PIM](#) and [Security](#) practices.

**2.1 Statement Of Privacy and Confidentiality Principles**

2.1 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

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

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 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.

<b>THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS</b>		
<b><u>AUTHORIZATION</u></b> Vice President Academic Development and Clinical Innovation	<b><u>DATE APPROVED</u></b> June 21, 2005	<b><u>DATE REVISED</u></b>

### 3. POLICY

#### 3.1 Scope

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

1. access to any personal information for which FH is considered the data [Steward](#), 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 laboratory services;
3. access to facilities for the placement, posting and/or distribution of research recruitment materials;
4. use of specialized equipment, and;
5. any other service requested of an External Researcher.

#### 3.2. Criteria for Providing Research-related Services

a. Before FH departments/units are permitted to provide research-related services to External Researchers, all 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/legally authorized individual 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 consent.
- 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 department/unit providing access to personal information.

<b>THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS</b>		
<b><u>AUTHORIZATION</u></b> Vice President Academic Development and Clinical Innovation	<b><u>DATE APPROVED</u></b> June 21, 2005	<b><u>DATE REVISED</u></b>

**3.3 Department/Unit Service Provision Requirements**

- a. Each department/unit 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 4.2](#).
- b. An annual report of the research-related services provided by the department/unit to External researchers shall be made to the FH Research 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 FH shall be controlled by the designated FH [Steward](#) for Information Management, Decision Support and Anatomical Pathology and any other designated information steward.

(ii) 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 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) FH 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 [Criteria](#) can be met.

**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.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

(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 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.

(iii) Tissue which is not identifiable in any way [i.e. anonymous] does not require consent.

(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 FH Anatomical Pathology.

**c. De-identification**

(i) Personally identifiable information shall be **Deidentified** to an appropriate degree or **Anonymized** before any disclosure or release is made to External researchers. This applies to both paper and electronic records and tissue.

(ii) Exceptions, in which personally identifiable information is released, shall be approved by the REB of the External researcher's institution, have evidence of written signed consent form the identified individual/legally authorized representative 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 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 [CHSPR].

**e. 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.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**f. 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 External Researcher for purposes other than the approved purposes.

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

**4. PROCEDURES**

*Procedures may be amended by the Vice President Academic Development and Clinical Innovation without further approval providing that 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 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<sup>3</sup>**

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”*

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<sup>3</sup> For the purposes of this section, Fraser Health is represented by the responsible Executive, the Vice President Academic Development and Clinical Innovation and the Director, Research.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

[FOIPPA](#) and the "Tri-council Policy Statement: Ethical Conduct of Research Involving Human Subjects" [TCPS](#).

b. FH 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 FH Director, Research shall oversee an annual review process to ensure that compliance with this Policy is maintained.

d. The FH Director, Research 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 DEPARTMENTS/UNITS**

**a. Consistent Process**

A consistent process shall be developed for access to physical charts, electronic records and other clinical information, i.e. tissue, for research purposes 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 consistent process across the Health Authority as under the direction of the FH steward for personal information.

**b. Evaluating And Approving Requests From External Researchers**

FH departments/units 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 FH department/unit will provide the External researcher with the department/unit's<sup>4</sup> requisition for research related services and cost recovery schedule. This requisition must be completed by

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

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

the External Researcher in order to have the request considered further by the department/unit.

At a minimum the FH department requisition should require External Researcher's name, affiliation, research study title, REB approval date, study period over which the service is required, details of the service/information/tissue required, whether the information required is identifiable, 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 department/unit, the FH department/unit 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. [TCPS Compliant](#).
- The institutional REB approved consent form OR waiver of consent with research protocol,
- The completed and signed Data Access Agreement, and;
- The <sup>5</sup>signed consent of the research subject(s) if consent was obtained. The signed consent sheet must include the study title that matches the study title on the consent form and the REB certificate of approval.
- 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 document that the consent is not able [i.e. impossible, not impractical or inconvenient] to be collected from the individual(s) to whom the information

<sup>5</sup> 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.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

belongs, the reasons why [i.e. proof] the research cannot be performed without the identifiable data and that any linkage, if applicable, is not harmful to the individual(s) concerned.

- **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. 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.
- **Adjudication**  
Concerns about the validity of the request and the documents provided should be brought to the attention of the Director, Research 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 FH department/unit shall de-identify [**Deidentified**] or anonymize [**Anonymized**] the requested information as per their standard procedures before release to the External Researcher.
- If the External Researcher has specified that identifiable information is required, the FH department/unit 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 FH **Data Access Agreement** 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.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

- 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 FH department/unit of the revocation.

(ii) When consent is revoked, the FH department/unit 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 FH Director, Research, the Vice President Academic Development and Clinical Innovation or any other FH staff, or the B.C. Privacy Commissioner's Office. Research policies and procedures shall be available on request by contacting the Director, Research.

ii. Queries/complaints shall be brought to the attention of the Director, Research who will investigate and respond to the person bringing forward the complaint, under the direction of the Vice President Academic Development and Clinical Innovation.

iii. The complaint, investigation, outcome and response to the person bringing forward the complaint will be documented and retained on file by the Director, Research.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

## 5. 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**

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.

### **Custody**

Refers to the physical holding of data.

### **Data Access Agreement [DAA]**

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 FH 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.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**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.

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.

**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 FH or an affiliated FH status.

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

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**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.

**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, 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 contact information. Information can be paper, electronic or photographic form, and tissue<sup>6</sup>, 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

<sup>6</sup> Source: Office of the B.C. Privacy Commissioner, June 2005

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

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.
- tissue [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 FH Researcher who is deemed to have overall accountability for the research conducted at a FH site.

**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”

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

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.

**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. FH] for that information.

**Security**

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

**Services**

FH departments/units that can either carry out a specific procedure, e.g. running diagnostic lab tests, or provide personal information, e.g. health records/tissue, to a non FH-affiliated researcher, i.e. External, who otherwise does not have that capability.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**Steward**

Within FH, individuals charged with the responsibility of maintaining ‘custody’ of sources of personal information, including tissue, include designated individuals within Information Management, Decision Support and Anatomical Pathology and other departments as applicable.

**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.

**Tissue**

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

**TCPS Compliant REB**

FH recognizes the TCPS compliant REB’s of public bodies. These include: 1) University of British Columbia affiliated REB’s including BC Cancer Agency and Providence Health Care REB’s; 2) Simon Fraser University REB; 3) University of Victoria REB; 4) Other B.C. academic and health authority REB’s.

Contact the FH Director, Research at [susan.chunick@fraserhealth.ca](mailto:susan.chunick@fraserhealth.ca) for information about other Canadian REB’s.

**6. REFERENCES**

**1. Audit of Electronic Health Information**

**2. CSA Model Code Principle #2: Identifying Purposes**

**3. CIHR**

Canadian Institute for Health Research Draft Privacy Guidelines

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**4. CSPI**

FH Policy "Confidentiality and Security of Personal Information"

Refer to:

<http://fhaweb/NR/ronlyres/ezlnb4uhxxhmoqr6vwwkrzmvwi25jegxi2d5akht5fzmfq3vbaw2dtbrgogllly3jgkvpqk4fbmntn/Confidentiality%2band%2bSecurity%2bof%2bPersonal%2blnformati.pdf>

**5. ETHICS**

FH Policy on "The Ethical Conduct of Research-related Activities 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](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](http://www.qp.gov.bc.ca/statreg/stat/F/96165_01.htm#part1)

As a public body, the FH, REB's and researchers are obliged to follow the regulations concerning the use of personal information for research related purposes under Bill 73 – Amendments to the Freedom of Information and Protection of Privacy Act Article 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.

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

**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.

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

**THE PROVISION OF RESEARCH-RELATED SERVICES TO NON-FH RESEARCHERS**

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

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.