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**CORPORATE POLICY, STANDARDS and PROCEDURE**



**POLICY TITLE**

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

**Catalogue Page Number**
#777

| **AUTHORIZATION** | **DATE APPROVED** | **CURRENT VERSION DATE** |
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| Vice President, Medicine | June 2005 | January 2019 |

## DATE(S) REVISED / REVIEWED SUMMARY

| Version | Date | Comments / Changes |
|---|---|---|
| 1.0 | June 2005 | Initial Policy |
| 2.0 | March 2014 | Policy Article 3.4 - Clarification regarding use of personal information if the FHREB has approved a waiver of consent. |
| 2.0 | March 2014 | Policy Article 3.5 c and c ii) – Clarification regarding access to charts and tissue by FHA and External Researchers. |
| 2.0 | March 2014 | Format; links updated. |
| 3.0 | June 2018 | "Subject replaced with "Participants" throughout. |
| 3.0 | June 2018 | 5 (c) Replaced "The Collection, Use and Disclosure of Personal Information for Research-related Purposes" with c. "The Ethical Conduct of Research and Other Studies Involving Humans " |

## INTENT / PURPOSE

As a public body and a **Steward** of personal information, the Fraser Health Authority [FHAA] 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 FHA, collected indirectly from other care providers and institutions during the provision of an individual's care at FHA, and/or collected by **FHA 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 FHA adheres include the Canadian "*Tri-Council Policy Statement*: *The Ethical Conduct for Research Involving Human Participants"* **TCPS**2 and the Canadian Institute for Health Research "*Best Practices for Protecting Privacy in Health Research"* **CIHR**.
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 **Participants** is protected by complying with the requirements of FOIPPA and meeting the standards of the TCPS.

## POLICY

### 1.1. 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 in paper, electronic or photographic form, or as tissue 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

FHA recognizes that although the participation of human Participants **Participant** is indispensable in order to conduct research that has the potential to benefit society as a whole, individual privacy rights must be protected while advancing appropriate and efficient information sharing to further research goals.

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 access, collection, use, disclosure of personal information about them. The right of privacy is exercised by providing consent.

FHA believes that the protection of personal information that is used for research purposes is a fundamental and integral part of every research process. FHA 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 **Substitute Decision Maker** 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 considered to be highly sensitive and requires security[1] 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 Participant 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 FHA or a **FHA Researcher** is considered the information **Steward**, and which is collected either:
1) directly for research purposes from research Participants, or,
2) indirectly from sources of information that were originally collected for purposes other than research, whether in FHA's custody or not.

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

2. all personnel involved in collecting, using, retaining, disclosing and/or destroying personal information in the custody of FHA or under the direction of the FHA Principal Investigator for research purposes. Personnel may include FHA employees, affiliated researchers, privileged physicians, other clinical staff, third party collaborators/sponsors, trainees, students, post-doctoral fellows and volunteers.

3. all FHA 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 FHA but the information belongs to the person about whom the information is recorded.

b. FHA 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 the confidentiality of their information.

**3.4 Defined Purposes**
Personal information collected by a FHA researcher shall be used solely for the purposes described in the FHA Research Ethics Board [FHREB] approved research protocol and to which the research Participant has consented or for which the FHREB has approved a waiver of consent.

**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 shall be obtained from the individual whose identifiable personal information is required for a research study as specified in the FHA Policy "The Ethical Conduct of Research-related Activities Involving Human Participants". This requirement applies to:

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

- the collection of information originally obtained for a purpose other than research, such as for care, during a research Participant's participation.

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 FHA REB for the consent waiver or for particular types of research described below.

**(i) Chart Reviews**

FHA 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 FHA or an External Researcher is requesting tissue from specified individuals, then consent from the next of kin must always be obtained by the FHA or the External Researcher unless a waiver of consent is provided by the FHA REB or 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 Participant, 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 described in the consent form given to patients prior to their consent.

**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 FHA disclose data which cannot be justified to fulfill the research purpose/objective.

b. Where FHA 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 or approval from FHA Privacy. Without prior consent to contact from the potential Participant, researchers shall not obtain data from care providers for this purpose. FHA Researchers shall not obtain the names of the potential research Participants from other public bodies or from patient care providers at FHA 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 FHA Anatomical Pathology.

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

**d. 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 Participant.

e. FHA data stewards, or research staff under the direction of a FHA **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 FHA REB, if its release meets applicable sections of the FOIPPA and of the specific protocol approved by the FHA 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 FHA 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 FHA data with other FHA data, or with external data shall either be undertaken by FHA or by a trusted third party.

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

**3.12 Security Safeguards**

**a. Protecting Confidentiality, Integrity and Availability**
**Security** controls shall be applied to personal information in the custody of a FHA 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 FHA Release of Information policy and procedures, through the FHA Research Office.

### 3.14 Openness
FHA 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
FHA shall enable an individual to exercise their right to challenge FHA'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 Participant, research Participant's partner/family member or member of the public can lodge a query or complaint with any FHA employee or privileged physician.

### 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 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 or the approval of FHA Privacy;
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 FHA Researcher for purposes other those approved by the FHA REB.

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

## DEFINITIONS

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

**'Authorization to Conduct Research' Letter**
Letter issued by the FHA Research Office signifying that the appropriate approvals applicable to the named study have been obtained including the FHA Research Ethics Board Certificate of Initial Approval.

**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 Participant/legal representative to take part in research after the procedures, costs, and potential risk and benefits have been explained in a manner that the Participant can understand. The written informed consent of Participants 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 Participant has made a decision to actively 'opt-in' to a research study. The consent of the Participants 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.

**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 FHA 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 Participant'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.

**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 FHA Policy "The Ethical Conduct of Research-related Activities Involving Human Participants".

**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 Participant 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.

**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 Participant identity and that identification of Participants is NOT possible by any means or by the information obtained from Participants.

**Personal Information**
Personal information is defined by FOIPPA as any recorded information about an identifiable individual other than business contact information. Information can be in paper, electronic or photographic form, or as tissue[2] about which can reasonably be said to identify an individual.

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

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 FHA researcher who is deemed to have overall accountability for the research conducted at a FHA site.
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:** FHA Policy on "The Ethical Conduct of Research and Research-related Activities Involving Human Participants"

Research involving human Participants 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.

**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 FOIPPA as well as industry standards and best practices and are responsible for its appropriate Collection, Use and Disclosure. FHA is responsible for setting policy in respect of data stewardship.

**Participant (formerly Subject)**
A Participant is a person about who a research investigation is being conducted for a purpose other than the sole purpose of benefiting the Participant 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 Participants. Donors of organs, tissues, and body fluids for research purposes and individuals, whose records are used for research, are considered to be Participants.

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

## PROCEDURE

### 4.1 Accountability And Obligations

To ensure that the obligations of FHA 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.

#### 4.1.1 FRASER HEALTH

a. Research requiring the collection, use and/or disclosure of personal information shall be conducted according to the requirements of the FOIPPA, 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 FHA Research Ethics Board.

b. FHA 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 FHA Research and FHA Privacy so that education and awareness regarding privacy and research will be included in educational material for FHA personnel.

c. FHA 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. FHA 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 FHA RESEARCH ETHICS BOARD

a. The FHA REB shall comply with the requirements of the FHA policy on "*The Ethical Conduct of Research and Other Studies Involving Humans* " 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.

#### 4.1.3 THE FHA DEPARTMENT/UNIT

a. Access to and the release of personal information, including tissue, to FHA Researchers under the custody of FHA shall be controlled by the designated FHA **Steward** for Health

Records, Health and Business Analytics, and Anatomical Pathology and any other designated information steward.

b. 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 to FHA 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 FHA ADMINISTRATIVE SUPERVISOR FOR THE RESEARCHER**

a. The Administrative Supervisor for the FHA 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 Participants 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 FHA RESEARCHER**

a. The FHA researcher shall detail accurately and completely the research purposes to which personal information is required in the study protocol, the FHA Application for Initial Ethical Review and study consent form or if a waiver of consent is required, compliance with the TCSP2 requirements for a waiver of consent.

b. The approval of the FHA REB and the FHA "Letter of **Authorization** to Conduct Research" must be obtained by the FHA Researcher and provided to the department/unit's data steward before access to personal information can be given by that department/unit.

c. The FHA researcher who requires access to personal information under the custody of FHA shall complete and sign the FHA **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 FHA researcher shall obtain the written signed consent of the research Participant /substitute decision maker for the collection, use and disclosure of any of their personal information for research purposes.

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

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

## 4.2 SPECIFIC PROCEDURES

### 4.2.1 Obtaining Consent to Contact

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

The consent-to-contact form does not require FHA 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 FHA 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, Health and Business Analytics 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 FHA steward for personal information.

b. Authority to release personal information of any kind is contingent upon the FHA Research Office issuing the FHA letter of "**Authorization** to Conduct Research". This letter signifies that the appropriate approvals have been obtained by the FHA Researcher and that the initiation of any research-related procedures including the release of personal information can commence. The FHA Researcher must provide a copy of this signed letter to the program/service holding the required information.

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

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

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

e. The FHA Program/service must retain a copy of the FHA 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.

### 4.2.4 Revoking Consent

a. If consent is revoked a status flag shall be set to 'deactivate' the research Participant's information. When that occurs the research Participant'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. The storage of identifiable personal information must meet FHA Privacy Requirements as referenced in the FHA Policy "Privacy and Security Requirements for Laptops, Notebooks, Blackberries and Other Mobile Technology".

b. Identifiable personal information should not be stored on C Drives unless appropriately protected and backed up as per FHA Information Security standards.

### 4.2.6 Complaints

a. This information is available on request in hard copy which can be obtained by contacting the FHA 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 FHA Research Ethics Board, the FHA Director, Research, the Vice President Medicine, FHA Privacy or the Office of the B.C. Privacy Commissioner.
c. 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 Medicine.
d. A documented process to track the status/outcome of complaints shall be put in place.
e. A reporting mechanism shall be in place to maintain records of all complaints and queries.

## 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 Participants.
Refer to:
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

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 Ethical Conduct of Research and Other Studies Involving Humans "
   d. Research Integrity Policy
   e. Whistleblower Protection
   f. Confidentiality and Security of Personal Information
   g. Conflict of Interest Policy