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CORPORATE POLICY, STANDARDS and PROCEDURE

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POLICY TITLE **RESEARCH**		**NUMBER** TBA
AUTHORIZATION Vice President, Medicine	**DATE APPROVED** June 2005	**CURRENT VERSION DATE** January 2014

DATE(S) REVISED / REVIEWED SUMMARY [1]

Version	Date	Comments / Changes
1.0	June 2005	Initial policy
2.0	January 2007	Policy Articles 3.9 - Addition of reference to the FHA Research Integrity policy.
2.0	January 2007	Policy Article 3.13 - Addition of requirements for the purchase of equipment from a grant funding agency.
2.0	January 2007	Policy Article 3.14 - Addition of requirement to acknowledge financial contribution from external funders in any type of publication.
2.0	January 2007	Policy Article 3.15 - Addition of requirement for clinical trial registration for clinical trial research.
2.0	January 2007	Policy Article 3.16 - Addition of requirement for retention and visibility of research subjects' signed consent forms in the medical record.
2.0	January 2007	Procedure 4.1.1 e) - Addition of reference to the FHA Research Integrity Policy.
2.0	January 2007	Procedure 4.2.2 f) - Addition of requirement for review of grant awardee eligibility.
2.0	January 2007	Procedure 4.2.2 h) - Addition of requirement regarding set up of research accounts for grant awardees.
2.0	January 2007	Procedure 4.2.2 i) - Addition of requirement for expenditure authorization for research grants.
2.0	January 2007	Procedure 4.2.2 j) - Addition of requirement for release of funds for funded new and ongoing research.
2.0	January 2007	Procedure 4.2.2 k) - Addition of notification requirement for change in researcher eligibility for research awards.
2.0	January 2007	Procedure 4.2.2 l) - Addition of financial reporting requirements for grant funded research.
2.0	January 2007	Procedure 4.2.2 m) - Addition of requirement for return of residual funds to the granting agency.
2.0	January 2007	Procedure 4.2.2 n) - Addition of requirement for review and

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		audit of financial transactions.
2.0	January 2007	Procedure 4.2.2 o) - Addition of requirement for controls to prevent over-expenditure by FHA researchers.
2.0	January 2007	Procedure 4.2.2. p) - Addition of conditions for withdrawal of approval of financial expenditures.
3.0	October 2009	Policy Article 3.11 b - Change in overhead rate for industry funded research.
4.0	November 2010	Policy Article 3.11 b - Change in overhead rate for industry funded research.
5.0	May 2012	Policy Articles 3.1 - Additional specifications for the scope of the policy.
5.0	May 2012	Policy Article 3.2 - Addition of criterion for permitted research regarding affiliated researchers.
5.0	May 2012	Policy Article 3.3 - Addition of criteria for types of studies, i.e. not research, excluded from the scope of the policy.
5.0	May 2012	Policy Article 3.6 - Revision of article to comply with FHA policy regarding signing authority.
5.0	May 2012	Policy Article 3.7 - Addition of requirement to acknowledge the Fraser Health Authority and the funding agency in publications.
5.0	May 2012	Policy Article 3.17 - Addition of specification for research accounts.
5.0	May 2012	Policy Article 3.18 - Addition of requirement to report institutional conflicts of interest related to research.
6.0	January 2013	Format; links updated
6.0	January 2013	Policy Article 3.1 iii and iv) – Clarification regarding Lower Mainland Consolidation FHA and non-FHA employees who conduct research
6.0	January 2013	Policy Article 3.2 f and g) – Addition of clarification regarding criteria for permitted research in FHA.
6.0	January 2013	Policy Article 3.5 b) - Clarification that FHA may publish research results.
6.0	January 2013	Policy Article 3.7 - Clarification added regarding adherence to the granting agency requirements for publication.
6.0	January 2013	Policy Article 3.13 – Clarification regarding uses of equipment

		subject to funding agency agreements.
6.0	January 2013	Policy Article 3.17 - Requirement regarding adherence by researchers to assigned responsibilities for cost centres for funded research.
6.0	January 2013	Policy Article 3.18 – Clarification regarding relationship between institutional conflicts of interest regarding research and the FHA Corporate Conflict of Interest Policy.
6.0	January 2013	Definitions: Data Access Agreement – Addition of FHA Privacy requirement.
6.0	January 2013	Procedure 4.1.3 (ii) – Reference to FHA Corporate Conflict of Interest Policy added.

INTENT / PURPOSE

The purpose of this policy is to:

1) describe the authority and obligations under which research activities can be conducted at Fraser Health [FHA][2] by FHA Researchers;
2) proscribe activities which breach generally acceptable standards of research conduct, and;
3) describe a process for handling allegations of research-related misconduct.

For the purposes of this policy, all definitions are found in Section 5 Definitions.

POLICY

FHA has a commitment to foster new ideas and innovation, to be open to new evidence-based research and to be focused on outcomes. To these ends, FHA supports research activities carried out by FHA Researchers in the belief that research can improve the quality of care provided to the FHA community[3]. The conduct of research within FHA is considered a privilege and not a right, such that in undertaking research, FHA and FHA researchers are accountable for exercising due diligence in carrying out the legal, ethical and fiduciary requirements for the conduct of any research study. FHA is committed to ensuring that FHA Researchers understand

[2] Fraser Health, FH or FHA when used throughout this policy and denotes the Fraser Health Authority.
[3] Fraser Health's Strategic Plan, October 2003, p. 2 and 37.

these obligations as well as their responsibility for carrying out the research according to scientific standards of reliability and validity. FHA will also ensure that the research activities conducted by FHA Researchers are fully transparent to the public, regulatory authorities and FHA staff.

3.1 Scope

This policy applies to the conduct of research as defined under Research and as outlined below:

i. the research is sponsored by FHA, or;
ii. the research is under the direction of and conducted by any FHA employee or physician with privileges at FHA in the capacity of principal investigator for FHA using any FHA property, including data, medical records or tissue, facility, and/or involving any FHA patients, clients, residents, or FHA employees/privileged physicians acting in their FHA capacity as research subjects, Researcher or;
iii. the research is under the direction of, conducted by, or involves any FHA employee or physician with privileges at FHA in connection with his or her FHA responsibilities, including those whose site of work is outside of FHA, such that the research may also be conducted outside of the FHA jurisdiction [see 3.3 below] unless under Lower Mainland Consolidation, the FHA employee is conducting research at another site, such that the non-FHA site policies apply and the research protocol is reviewed and approved by that site's Research Ethics Board (Refer to the FHA Policy "The Ethical Conduct of Research and Other Studies Involving Human Subjects), or;
iv. the research is under the direction of and conducted in FHA by non-FHA employees/physicians who have Affiliated status with FHA in the capacity of principal investigator [e.g. faculty with an academic appointment at a FHA 'affiliated' post-secondary education institution or Lower Mainland Consolidated personnel], or;
v. a portion of the research is being carried out by a FHA researcher (i.e. FHA employee/privileged physician) as a service to a non-FHA researcher, or ;
vi. a portion of the research involves any FHA employee or privileged physician in the role of co-investigator, or;
vii. the research involves the use of FHA's non-public information or;
viii. any portion of the research funding is administered by FHA.

3.2 Criteria For Permitted Research

a. The FHA Principal Investigator (PI) for any study conducted at a FHA site or in connection with his or her FHA responsibilities shall be directly affiliated with FHA, by being either directly employed, having privileges, or by having met the requirements [Application] to obtain affiliated status. Affiliated researchers shall have an academic appointment at a recognized academic institution or accredited healthcare organization. Refer to Procedures: General Procedures 4.3a.

b. Students who are not FHA employees or who are medical residents shall conduct research for the purposes of fulfilling academic requirements as a co-investigator under the supervision of a FHA Principal Investigator who has agreed to assume responsibility for the conduct of the study.

c. The FHA Principal Investigator assumes responsibility for all Co-Investigators involved in their research study related activities, including development, conduct, analysis and reporting, whether these are FHA Researchers or researchers not directly affiliated with FHA [i.e. External].

d. Research involving human subjects shall be carried out according to the FHA Policy "The Ethical Conduct of Research and Other Studies Involving Human Subjects".

e. Studies such as quality assurance, quality improvement, program evaluation and case reviews that intentionally include a research component shall be considered research for the purposes of ethical review. Refer to FHA Policy *"The Ethical Conduct of Research And Other Studies Involving Human Subjects"*.

f. For greater clarity, FHA does not grant access to the use of its internal information or any patient, resident, client or family information without following the formal approval processes established for this purpose and which may require submissions to the FHA Research Ethics Board.

g. FHA shall not be associated with, responsible for or linked by any means to any independent research unless prior written approval is given by the organization.

3.3 Excluded Studies

The types of studies excluded from the scope of this policy include:

- projects normally administered in the ordinary course of the operation of FHA and that are undertaken exclusively for assessment/planning, management or improvement purposes, such as quality assurance, quality improvement or program evaluation activities;
- collection of information from FHA authorized personnel who have the authority to release non-confidential organizational information about FHA such as policies, procedures, professional practices, service delivery, and statistical reports;
- research involving only the use of published or publicly available information or materials, performances or archival materials;
- involves the participation of FHA employees/privileged physicians as research subjects or as researchers and which falls outside of their prescribed work time and / or broad fiduciary responsibilities to FHA.

3.4 Research Requiring Executive Authorization

a. The following types of research, including but not restricted to, will not normally be carried out at FHA:

- research, involving animals or biohazardous substances other than approved radioisotopes;
- research in which an intention to fully publish the results is prohibited in a contractual agreement with the Sponsor/collaborator;
- research carried out by non-FHA affiliated researchers, and;
- research that is not in the public interest.

b. Special authorization shall be required from the Vice-President [VP[4]] to contemplate research projects that are outside the criteria for permitted research as defined in Section 3.2.

3.5 Adherence to Standards of Integrity, Accountability and Responsibility

a. FHA Researchers are responsible for ensuring that their approved research studies meet the highest standards of scholarly and scientific rigour in addition to ensuring that they are accountable for meeting all legal, ethical and fiduciary obligations in carrying out the approved research. This includes all activities related to obtaining the appropriate approvals to conduct

[4] VP is used throughout the text to denote the authorizing VP.

research, all activities related to collecting, recording and analyzing data and in presenting, reporting and publishing results, and all requirements related to the disclosure of potential conflicts of interest.

b. FHA Principal Investigators for specific studies are responsible for ensuring that the terms and conditions of an awarded research grant or of an executed research contract or of a confidentiality agreement are complied with at all times. Researchers agree that the nature of their research activities and the funding received and source of funds may be published by Fraser Health in any summary information provided to Fraser Health Communities.

c. FHA Principal Investigators shall be financially responsible for all overspending on contracts or on grant accounts.

3.6 Signing Authority

a. Every application to obtain an award in the form of grants from granting agencies, every contract specifying funding by a for-profit sponsor and every contract entered into for collaborative research shall be approved and executed by an authorized signing officer in accordance with FHA policy.

3.7 Publication

a. Results of research undertaken by FHA Researchers shall be made public and adhere to the publication policies of the granting agencies, where applicable.
(i) FHA Researchers shall list the “Fraser Health Authority” as the professional affiliation or institution on all publications resulting from research conducted at FHA.
(ii) All publications arising from grant funded research shall acknowledge the funding agency.
(iii) All research manuscripts shall be reviewed by the Department of Evaluation and Research Services prior to submission to journals for consideration for publication.

b. The following qualifications pertain to research with commercial interests such as industry sponsored research.

(i) Where the sponsor has industrial or commercial rights which it wishes to protect arising out of the research study, or where the sponsor wishes to be given an opportunity to publish the

results of the research before publication by the FHA Principal Investigator or to approve the publication in advance of publication by the FHA Principal Investigator, time for such protection or publication may be given provided that:
1. the FHA Principal Investigator shall in any event be free to publish after twelve months from the submission of the final report to the sponsor or termination of the project, whichever is later.
2. if there is any change in the sponsor's publication from the original report, the name of FHA and the FHA Principal Investigator/co-investigator(s) shall not be used in connection with the publication without the written consent of FHA and the FHA Principal Investigator/co-investigator, and;
3. publication of a thesis by a FHA employee who is also a graduate student in an academic program shall not be delayed by such restriction.

ii) In exceptional circumstances, FHA may authorize the withholding of publications for a period longer than twelve months from the submission of the final report to the sponsor, but in no case shall publications be delayed longer than twenty-four months from the submission of the final report to the sponsor.

3.8 Monitoring of Research

FHA shall have the authority to put into place procedures for monitoring ongoing research.

3.9 Investigation of Research Misconduct

a. FHA shall investigate any allegation of research misconduct in a timely, impartial and accountable manner and shall take appropriate action should it find that misconduct has occurred.

b. The FHA Director, Research shall ensure that an investigative process is established. Refer to Procedure 4.5 and to the FHA Research Integrity Policy for further detail.

3.10 Provision of Research-related Services

a. FHA departments/units may decline to provide research-related services to FHA Researchers that are part of the FHA Research Ethics Board approved research protocol for a particular study. The decision to provide the research-related service shall take in account the mandated operational demands of that department/unit so that the delivery of services that support standard patient care is not interrupted. Refer to General Requirements b.

b. The provision of research-related services shall be made on a cost recovery basis as determined by each individual department/unit for all funded studies, regardless of the funding source.

c. The provision of research-related services for studies that do not have a funding source shall be at the discretion of the individual department/unit in so far as the provision of those services does not interrupt the standard operation of that department/unit.

d. FHA departments/units providing research-related services shall submit an annual report of the provision of those services to the FHA Research Office.

3.11 Recovery of Indirect Costs

a. On the principle of cost recovery, FHA shall recover indirect costs of research incurred to the organization by the conduct of industry sponsored research or from government departments and other granting agencies. The Vice President shall have the authority to waive this requirement.

b. The schedule of indirect costs shall be set by the Vice President in consultation with FHA Finance. The overhead rate for indirect costs for industry funded research shall be 25% with the exception of industry funded research that is managed by FHA physicians which shall be set at 10%.

3.12 Compensation

a. Principal investigators may be compensated for the performance of services in direct connection with a research contract.

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3.13 Equipment

a. Subject to the terms of grant funding agreements, equipment and material purchased or collected with grant funding from a non-commercial funding agency shall belong solely to FHA.
(i) Proceeds from the sale of any grant-funded equipment or material shall be used for research-related purposes only.
(ii) FHA shall give permission to any grant recipient who is moving to another Canadian institution and who wishes to take an unexpended Equipment Grant or to move equipment or other material purchased with grant funds, to do so.
b. Equipment not in use by the grant recipient shall be made available for use by other FHA personnel for their research.
(i) FHA may charge fees to these users should there be a requirement to recover direct costs incurred.
c. A registry of research equipment shall be maintained.

3.14 Acknowledgement of Contribution

a. The financial contribution for research of any funding agency or commercial sponsor shall be acknowledged by FHA in any media release, publication, presentation or other public mention.

3.15 Clinical Trial Registration

a. Clinical trials which prospectively assign human subjects to intervention and comparison groups to study the cause-and-effect relationship between the medical intervention and the health outcome shall be registered by the industry or FHA investigator sponsor with a registry that meets the requirements of the International Committee of Medical Journal Editors.

b. Medical intervention includes drugs, devices, surgical procedures, behavioural or management studies which have the intent to modify a health outcome, with the exclusion of Phase 1 clinical trials.

3.16 Subject Safety

a. Consent Form Retention
The signed informed consent for a study involving FHA inpatients or outpatients shall be maintained at the front of the medical chart in such a way that it is visible.

3.17 Research Accounts

a. In accordance with the financial requirements of agencies that have provided awards to FHA researchers who are employees/privileged physicians, all research awards and funds received by FHA employees/privileged physicians acting in their capacity as a FHA principal investigator for a specific study shall be held in a designated research account under the Department of Evaluation and Research Services with the exception of funds received by FHA privileged physicians for the conduct of industry sponsored research, unless requested to do so by the physician principal investigator for a study.

b. FHA principal investigators shall abide by assigned responsibilities for their research cost centre(s).

c. All FHA principal investigators shall notify the Department of Evaluation and Research Services of any proposals being submitted for funding to external agencies.

3.18 Reporting Institutional Conflicts of Interest

a. FHA shall ensure that real, potential or perceived institutional conflicts of interest, as defined by the FHA Corporate Conflict of Interest Policy that may affect research are reported to the Fraser Health Authority Research Ethics Board (FHA REB). The FHA REB shall consider whether the institutional conflict of interest should be disclosed to prospective participants as part of the consent process for the applicable study.

DEFINITIONS

Affiliated Researcher
An affiliated researcher is an individual who does not have a direct relationship with FHA by virtue of employment or being engaged as a privileged physician but who has met specific

requirements for applying for this status and who has been granted this status by the Vice President, Medicine.

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. These approvals include:
- FHA Research Ethics Board Certificate of Initial Approval
- FHA Department Agreement For Providing Research-related Services – if services are required
- For clinical trials: Health Canada Letter of No Objection
- For industry sponsored clinical trials: Executed Clinical Trial Agreement

Confidentiality Agreement

A confidentiality agreement may also be called a non-disclosure agreement. These agreements:

- define the applicable confidential information and any time limits for maintaining confidentiality;
- specify terms by which either party's confidential information is transferred to the other party;
- the sponsor, FHA, and principal investigators are signatories to the agreement;
- other requirements of the parties.

Confidential information excludes information that is: already known/independently developed by the recipient; disclosed to the recipient by a third party without an obligation of confidentiality; in the public domain at the time of disclosure or during terms of agreement; or disclosed pursuant to judicial or administrative order.

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.

A co-investigator may be a FHA Researcher or a researcher who is not affiliated with FHA. The FHA principal investigator is responsible for the conduct of the co-investigator.

Contracted Services Employee
A contracted services employee is an employee hired within the terms of FHA Human Resources. Refer to:
http://FHAaweb/Tools+and+Resources/HR+Tools/Managers+Guide/Contractor-Services+Contracts.htm

Contract
A research contract is an agreement to perform research or research-related activities under specified negotiated conditions in exchange for payment of direct costs and indirect costs.

FHA research contracts for industry sponsored clinical trials are tri-partite agreements between the industry-sponsor, FHA, and the principal investigator for that study.

Contracts between FHA and a collaborating partner are between FHA and the collaborating partner usually.

Data Access Agreement [DAA] Form
A DAA sets out conditions under which information, including tissue, may be used and managed over its lifetime and is required by FHA Privacy for the release of any data (identifiable or not) . The conditions are applied to the use, linkage, and subsequent re-identification (if possible), protection, destruction, archiving, or return of such information as appropriate to the level of identifiably of the information, the sensitivity of the information and any other criteria which FHA may wish to consider

Department Agreement for Providing Research-related [DAR] Services Form
The DAR Form is available from the FHA Research Department and must be used by FHA researchers who require services from FHA departments in order to carry out their research.

The form must be completed with all applicable signatures by all FHA researchers requiring services from FHA departments and returned to the FHA Research Office before the FHA 'letter of authorization' to conduct research can be issued.

Direct Costs
Direct costs are costs of a research study which can easily and accurately be identified as such. Examples include but are not limited to salaries, wages and benefits of research personnel,

physician compensation for services provided as the investigator (s), materials and supplies, travel, equipment and rental of space and costs for providing research-related services, such as lab tests, imaging procedures, release of personal information including tissue, pharmacy services, information technology services, use of operating rooms and other FHA space.

External Researcher
An external researcher is a researcher who does not have an affiliation with FHA and who is conducting research in a non FHA capacity.

Grant/Unrestricted Grant in Aid
- A grant or an unrestricted grant in aid is funding received from any public or private source, including granting agencies, government, industry, FHA, gifts, to pay for part or all of the costs of a research study. There are no conditions attached to the funding. The following criteria apply:
- Supports the general research activities of an individual researcher or group of researchers
- No specific result required or expected by the funding agency
- No rights (i.e. inventions or other intellectual property) accrue to the sponsor
- No restriction on publication of results
- No restriction on use of funds
- No information confidential to the sponsor shall be accepted
- Funds are paid up front or by installments in advance

Industry-sponsored Clinical Trial
- Sponsor initiated for Phase I, II, III, IV
- Sponsor writes the protocol and owns the compound or device
- Agreements negotiated and signed by principal investigator, sponsor and FHA
- Publication may be temporarily restricted (within clearly defined limits) to protect commercial interests of sponsor. In the case of a multi-centre study, publication may be restricted until the study has been reported in full by all centres.
- Confidential information provided by the sponsor shall be protected by FHA and the principal investigator.
- Indemnification and insurance provisions shall be included in the agreements.
- Amendments to the protocol must be approved by the sponsor and the FHA Research Ethics Board.

Amendments to the clinical trial agreement must be approved by FHA.

Independent Contractor
Refer to:
http://fhpulse/benefits_and_people_resources/paying_you/Management%20%20Management%20Support%20Excluded/Independent%20Contractor/rc4110-06e.pdf

Indirect Costs
Indirect costs of a research study are costs which cannot be directly attributed to it, usually because they are incurred for infrastructure support from an institution, such as Fraser Health. Examples include but are not limited to building use and depreciation, equipment depreciation, physical plant and maintenance (including utilities, hazardous waste disposal, security), insurance, financial administration, material services and libraries.

Institutional Conflict of Interest
An institutional conflict of interest involves a conflict between at least two substantial institutional obligations that cannot be adequately fulfilled without compromising one or both obligations. Conflicts may occur when pursuing particular goals, for instance, the pursuit of two different "goods," such as an effort to obtain general infrastructure funding from a donor that conflicts with an effort to promote research that the donor does not wish to support.

Principal Investigator
The principal investigator is the researcher who is deemed to have overall accountability for the research conducted at a FHA site, despite who is the awardee of a grant for grant funded studies. The principal investigator is always considered the supervisor of the research team.

Investigator-initiated Clinical Trials

- Protocol written by a researcher
- Funding provided with or without "free" study drug or device with no deliverables
- Drugs or devices may be provided by the company or may be purchased with the company funds,
- **If this is a new drug or device, or new use for an existing drug the Principal Investigator must apply to Health Canada for approval, and therefore, is considered to be the Sponsor.**
- Ownership of any intellectual property vests in FHA.

- Company can be granted an option for a royalty-bearing license to such property
- Publication may be temporarily restricted (within clearly defined limits) to protect commercial interests.
- Confidential information provided by the company shall be protected by FHA to the best of its ability.

Research Involving Human Subjects

- 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, when those individuals are the focus of the research;
- 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 biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells that have been derived from living and deceased individuals.

Research-related Services

Departments/units/areas that may be asked to provide research-related services include: Decision Support, Health Records, Laboratory Medical Services, Information Technology, Anatomical Pathology, Medical Imaging, Surgical suites, Pharmacy and patient care services in acute and community sites.

Research Misconduct

Misconduct can include a range of actions that affect the participation of the research subjects, the integrity of the research results and researchers involved in the study. Misconduct can arise because of incompetence, carelessness, negligence and intentional dishonesty.

Misconduct can include: plagiarism [misrepresenting the thoughts, writings, or inventions of another as one's own], fabrication [inventing or forging research data or citations] or falsification [alteration, selective omission or misrepresentation] of research data; conflict of scholarly interest, such as suppressing the work of another researcher; failure to obtain ethical

approval for research [including initial approval, approval for amendment and annual renewal], significant protocol deviations that resulted in harm to a research subject; improper conduct with respect to professional codes of practice.

Misconduct does not include any matter involving only an honest difference of opinion, mistake or an error of judgment.

Sponsor
An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. See Industry-sponsored Clinical Trial and Investigator-initiated Clinical Trial.

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.

PROCEDURE

4.1 Accountability and Obligations

To ensure that the obligations of FHA are discharged in such a way that the rights of research subjects are protected, the following institutional and individual responsibilities are established and recognized.

4.1.1 FRASER HEALTH[5]

a. Setting Expectations
FHA shall be responsible for developing awareness and understanding among FHA Researchers and FHA staff of the need for the highest standards of integrity, accountability and personal

[5] For the purposes of this section, Fraser Health is represented by the responsible Executive, the Vice President, Medicine and the Fraser Health Department of Evaluation and Research Services.

responsibility when involved in carrying out research-related activities. Training programs that include promoting awareness of regulations, policies and other relevant standards that pertain to research will be offered to FHA Researchers and staff.

b. Compliance with Legislation, Policies and Standards

FHA complies with all applicable legislation, policies and standards for best practices that apply to the conduct of research by FHA researchers and that at a minimum include:

1) legislation, including the **Health Canada** *"Food and Drug Act Regulations"*, the *B.C. "Freedom of Information and Protection of Privacy Act"* [**FOIPPA**] and the **United States** *"Common Rule* [CFR 45.46] *";*

2) policies, including the Canadian "*Tri-Council Policy Statement on the Ethical Conduct of Research Involving Human Subjects"* [**TCPS**], applicable granting agency policies, the *FHA Policy on the "Ethical Conduct of Research-related Activities Involving Human Subjects"* **Ethics Policy** [Approved 2005 April 12] and other FHA policies that govern research activities.

3) standards including the World Medical Association "*Declaration of Helsinki"* [**Helsinki**], the United States *"Belmont Report"* [**Belmont**] and the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use *"Good Clinical Practice: Consolidated Guideline"* [**ICH GCP**].

c. Authorization to Conduct Research

(i) Research is permitted to begin only when the FHA letter of "Authorization to Conduct Research" is released to the FHA principal investigator by the FHA Research Office.

b. The authorization shall be contingent upon receipt of the applicable approval documents by the FHA Research Office as listed in approvals under Section 4.2 **Specific Requirements.**

c. The authorization is required before FHA Finance is permitted to release any funds to the FHA Researcher that are held in FHA accounts.

d. Funded Research

(i) FHA will follow generally accepted accounting practices [GAAP] regarding all financial transactions.

(ii) Disbursement of all Research Grants/Contracts shall be done under sound financial internal controls.

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(ii) Contracts

Contracts which are binding on FHA shall include terms and conditions that meet FHA requirements for managing risk and are congruent with FHA requirements relating to ethical review, privacy and confidentiality as governed by the FHA Policies on *"The Ethical Conduct of Research And Other Studies Involving Human Subjects"* and the *"The Use, Collection and Disclosure of Personal Information for Research-related Purposes".*

(iii) Grant Accounts and Uses

FHA may establish separate research accounts for sources of funding derived from grants awarded to FHA Principal Investigators. Financial statements, if required by the granting agency shall be prepared by FHA Finance according to their records. FHA Finance shall retain original invoices/vouchers on file for audit purposes.

Research staff engaged as an independent contractor shall meet the requirements of FHA Human Resources for this category of employment. The study budget must be adequate to absorb the full costs of all compensation for research staff that will be charged to the account, including allowance for benefits for those who are deemed to be FHA employees.

All honoraria, professional fees, salaries or payment for services shall be paid to individuals through the FHA Accounting Services.

(iv) Opening of Accounts for Awarded Grants

The opening of a research account shall be authorized in writing by the Director, FHA Research. The Letter of Authorization to Conduct Research for the grant awarded study shall be issued to FHA Finance as confirmation that the applicable approvals are in place and that the award account can be opened.

(v) Use of Funds from Grant Accounts for Initial Study Year

FHA Finance shall only make awarded funds available for the first study year from the deferred grant account upon receipt of a copy of the FHA letter of "Authorization to Conduct Research" from the FHA Research Office. Refer to **Requirement 4.2.1.**

Should FHAREB approval not be obtained within six months of the award date, the funding agency shall be informed of the delay and the reason for the delay.

(vi) Use of Funds from Grant Accounts for Subsequent Study Years

Use of awarded funds for subsequent study years shall be contingent upon a letter of confirmation by the Director, FHA Research that the ethical approval for the research study funded by that grant has been renewed and that a FHA Research Ethics Board certificate of annual renewal has been issued to the grantee.

Annual renewal of ethical approval must be obtained for each year that is covered by the award. Refer to **Ethics Policy**.

e. Research Misconduct – Refer to FHA Research Integrity Policy

(i) Investigation

Misconduct as defined in the FHA Research Integrity Policy shall be investigated upon the findings of the initial inquiry that research misconduct occurred according to the criteria laid out in the Research Integrity policy.

(ii) Suspension of Research Activities

FHA shall order any approved research to be suspended immediately if there is any serious or continuing non-compliance with the FHA Policy *"The Ethical Conduct of Research and Other Studies Involving Human Subjects"* such that:

- research is not being conducted in accordance with the current REB approved protocol, or;
- research is not being conducted in accordance with applicable rules and regulations; or
- research is not being conducted in accordance with the FHA REB's requirements, or;
- research has been associated with serious harm to subjects, or;
- research creates a potential threat to the safety and welfare of patients, or;
- research creates a potential threat to the safety and welfare of others.

(iii) Reporting Noncompliance

FHA shall promptly report any serious or continuing noncompliance with the FHA Policy on the *"The Ethical Conduct of Research and Other Studies Involving Human Subjects"* [6] and any suspension or termination of FHA REB approval to Health Canada and the funding body as applicable, and in the case of United States federally funded research to the United States Office of Health Research Protections.

[6] This includes Canadian regulations governing clinical trial research and United States federal regulations governing U.S. government funded research.

(iv) Disciplinary Measures
Principal Investigators and co-investigators who have failed to exercise reasonable care in directing and supervising researchers and research staff who have committed research misconduct shall share in the responsibility, accountability and consequences of these events.

f. Transparency
FHA shall make available research-related records of all approved research studies for scrutiny by regulatory authorities or if required by law. The public shall have access to lists of ongoing research activities.

4.1.2 THE FHA ADMINISTRATIVE SUPERVISOR FOR THE RESEARCHER

a. The Administrative Supervisor (e.g. Department/Division Head/Manager) for the researcher shall ensure that those who conduct, and those who are being trained to conduct, such research understand their legal, ethical and fiduciary responsibilities for the conduct of such research, receive appropriate training in the skills necessary for the conduct of such research, and carry out research in compliance with FHA policies that govern research. This type of training includes promoting an awareness of regulations, policies and other relevant standards (e.g., legal, professional and institutional) pertinent to the particular area of research.

b. The Administrative Supervisor shall approve the initiation of any research in the department/unit under his/her supervision.

c. The Administrative Supervisor shall fulfill his/her obligations as specified in the FHA Policy on *"The Ethical Conduct of Research and Other Studies Involving Human Subjects"*.

4.1.3 FHA RESEARCHERS

a. Research Conduct
(i) All FHA researchers involved in carrying out a study are responsible for the intellectual quality, scientific validity and reliability, and ethical integrity of their work. Specifically with respect to the latter, all researchers are responsible for implementing their responsibilities under the FHA Policy on *"The Ethical Conduct of Research and Related-activities Involving Human Subjects"*.

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(ii) All FHA researchers abide by the FHA Corporate Conflict of Interest Policy and shall ensure that any conflict of interest, financial or otherwise, is disclosed prior to obtaining ethical approval to conduct the research and shall ensure that any conflict of interest that arises during the conduct of the study is disclosed.

(iii) All FHA researchers shall ensure that all primary and secondary sources of information obtained for research purposes meets the requirements of the FHA Policy on *"The Collection, Use And Disclosure Of Personal Information For Research-Related Purposes".*

(iv) A verifiable record of all primary data in complete, original and chronological form and the results from analysis of all secondary data including documentation of its source shall be retained for a period of five years upon completion of research studies that are not regulated by Health Canada.

The retention period for all clinical trial research which is regulated by Health Canada is twenty-five years following close-out at the FHA site.

(v) The FHA Principal Investigator for a research study shall be accountable for supervising the conduct of all co-investigators and research staff under his/her supervision to ensure compliance with this and other FHA polices governing research. Specifically, the Principal Investigator for any study is accountable for:

- for the quality and ethical integrity of the work carried out by other co-investigators and research staff and shall document and provide to research team members a list of the conditions under which the research is being conducted as well as their specific roles and responsibilities for carrying out required work;
- ensuring that everyone working on the research study is aware of and agrees to comply with all applicable terms and conditions of any awarded grants or of any contracts, should these apply;
- for the training, management and supervision of research personnel;
- submitting reports and other deliverables in the form and by the dates specified as a condition of awarded grants or contracts;
- effective economic management of the study including authorizing expenditures in accordance with the budget outlined either in the grant or contract and the requirements of FHA Finance;

- informing FHA Research and funding agencies, as applicable, of any change in eligibility status or in the nature of the research that may have an impact on the approvals for research;
- acknowledging any financial support received;
- following all relevant FHA policies and procedures;
- notifying FHA Research of the completion of the research study or failure to complete, and;
- registering clinical trials with the US National Library of Medicine via ClinicalTrials.gov or Controlled-trials.com if the FHA Principal Investigator is also the sponsor of the clinical trial and for updating the registration information when the trial is complete or results are published. For multi-centre studies the FHA site Principal Investigator shall verify that the trial has been registered by the industry sponsor (or the overall Principal Investigator if the study is run from another site).

b. Obtaining Required Approvals to Conduct Research

(i) The FHA principal investigator must seek to obtain the written permission of the senior administrator for his/her unit for any research-related study proposed by him/her or proposed by a student working under his/her direction that could be defined as a research study. This permission must be obtained before any applications for ethical review and/or funding are made.

(ii)The FHA Principal Investigator shall obtain all the necessary approvals for conducting research as listed under Section 4.2.1 **General Procedures** and submit these to the FHA Research Office in order to obtain the FHA letter of "Authorization to Conduct Research".

(iii) The FHA Principal Investigator shall not permit any research-related activities to begin until the FHA letter of "Authorization to Conduct Research" for the applicable study has been received from the FHA Research Office.

c. Use of Research Funding

(i) All FHA researchers who are the recipient of any funds received for conducting research, including grants, contracts, and unsolicited donations, shall be responsible for the proper management of all funds received from the funding source and shall sign the Department of Evaluation and Research Services "Research Grant Award Accountability" document. Specifically, this includes ensuring that all expenditures conform to the approved budget, with

all terms and conditions of the grant or contract, with all regulations of the funding agency, with the policies of FHA Finance and any other FHA departments that are involved in the administration of the funds, and with the requirement for annual ethical approval.

(ii) Requests for new accounts or amended accounts, such as budget increases to existing accounts, must be made in writing.

d. Ownership of Results and Publication

(i) FHA researchers shall reach a mutual understanding about ownership of the research results with the research collaborators regardless of the source of funding, before research is undertaken.

(ii) The FHA Principal Investigator shall endeavour to publish the results of the research, subject to qualifications listed in Article 3.7 Publication.

(iii) The FHA Principal Investigator shall ensure that appropriate recognition, including authorship, is given only to those researchers:

- who have made an intellectual or practical contribution to the research study, and/or,
- who may have permitted their unpublished work to be used in the development of the research study.

(iv) The FHA Principal Investigator shall ensure that all researchers involved in any research study which is submitted for publication and who are listed as authors shall see and approve the manuscript before it is submitted.

(v) All researchers, listed as authors shall be expected to understand the significance of the research conclusions and share responsibility for the content and reliability of the reported information.

(vi) The FHA Principal Investigator shall ensure that research manuscripts submitted for publication reflect best practices in research reporting and adhere to current research reporting guidelines such as those listed with the EQUATOR Network http://www.equator-network.org/home/

(vii) Internal review by the Research Office is required before manuscripts arising from research are submitted for publication or review and consideration for publication in peer reviewed and non-peer reviewed journals.

(viii) The internal review and distribution of comments to the Principal Investigator will be coordinated through the FHA Research Office.

(viiii) All researchers shall disclose any potential intellectual property arising from their research.

4.2 Specific Requirements

4.2.1 Approvals Required For FHA Letter of 'Authorization to Conduct Research'

a. The FHA Principal Investigator for a study must ensure that the following approvals have been completed and/or submitted to the FHA Research Office **BEFORE** research-related procedures are initiated.

Mandatory approval for ALL types of research studies:
- FHA Research Ethics Board Certificate of Initial Approval

Mandatory approval for ALL Health Canada clinical trials:
- Health Canada Letter of No Objection

Mandatory documents for ALL Industry-sponsored clinical trials:
- Executed Clinical Trial Agreement

As Applicable:
- Completion of FHA 'Department Agreement For Providing Research-related Services' Form [DAR] for services required from FHA departments/units. Refer to **General Requirements b** .

b. Upon receipt of the applicable approvals, the FHA Research Office shall sign and release a 'Letter of Authorization to Conduct Research' to the Principal Investigator. This letter is required before any research-related can begin.

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4.2.2 Grant Funded Research

The following procedures apply to:
1) every new application for external funding for research-related activities;
2) requests for renewal/supplementation of funding to existing projects, and;
3) letters of intent.

a. Internal Review Of Applications For Funding

(i) Internal review by the Research Office is required before all new applications for funding are approved for signature by FHA in order to confirm the principal investigator's eligibility to apply for a grant according to the funding agency's eligibility criteria and to ensure that the process for obtaining the appropriate FHA approvals is/has been implemented.

(ii) The Principal Investigator must submit one copy of the proposed research for internal review prior to submitting the application to a granting agency.

(iii) The internal review and distribution of comments to the Principal Investigator will be coordinated through the FHA Research Office.

b. Required Signatures For Applications

(i) Every application for funds from an external non profit source (e.g. federal granting agency) shall be signed in the following order: applicant, applicant's immediate supervisor, Vice President Medicine or designate.

(ii) The Principal Investigator must ensure that the required signatures are obtained prior to submitting the application to the granting agency.

(iii) The signatures affirm that:
- the applicant is eligible to apply;
- the information in the application is complete and accurate to the best knowledge of the applicant;
- the applicant has sufficient space and resources to do the research;
- the application has been signed by the appropriate FHA authorities;
- if an award is made, FHA is able and willing to administer the funds on behalf of the granting agency in accordance with the guidelines of the granting agency;

- if an award is made, the awardee agrees to abide by the award regulations of the granting agency;
- if an award is made, FHA will not release funding to the awardee until all award conditions of the granting agency and the FHA have been met, including regulatory requirements;
- if an award is made, the awardee will use the award only for the purposes for which the award was made, and;
- if an award is made, the awardee will notify FHA Research and the granting agency if there is any change in their status that affects the award.

c. Copies of Applications

Two copies of the application for external funds from a granting agency shall be provided to the FHA Research Office for review and final signature. Note that all other required signatures must first be obtained. The signed copy shall be returned to the applicant within 3 business days of receipt for submission to the granting agency.

d. Budget and Travel Expenses

Budget, including requirements for classification and salary levels of research personnel and travel expenses, shall be in accordance with the regulations of the granting agency and/or FHA requirements.

e. Notification of Research Awards Received

All FHA researchers who receive awards, either in the form of grants or unsolicited donations, shall notify the FHA Research Office and provide the office with a copy of the award notice/letter plus copies of any other documents concerning the regulations or conditions governing the use of grant funds.

f. Review of Awardee Eligibility

Upon receipt of the award notice, the FHA Research Office shall review the status of the awardee and the certification/approval status of the study to confirm eligibility to receive the award.

g. Receipt of Awarded Grant Funds

(i) All cheques awarded to FHA Researchers must be made payable to the “Fraser Health Authority”.

(ii) Cheques received by FHA awardees or departments must be forwarded to the FHA Research Office for deposit to the appropriate FHA Common Grant and Award account.
(iii)FHA personnel shall not accept personal cheques for research support.

h. Research Accounts

(i) Individual research accounts shall be set up by source of funding for individual research studies that require institutional agreement for the grant to be awarded.

i. Expenditure Authorization

(i) Expenditures shall be initiated or authorized only with the grant/award recipient's delegated authority. The Finance Office shall maintain a list of delegated authority for each principal investigator.
(ii) All claims shall have the grant recipient's or delegate's signature.
(iii) The signatures certify that:

- all expenditures on the claim are for the purpose for which the grant was awarded;
- the charges included on the claim have not been claimed for reimbursement from other sources; and
- reimbursements for expenditures received from other sources or institutions shall be disclosed to FHA.

(iv) All expenditures shall be for those expenses incurred after the start of the agreement and before the end of the agreement, unless otherwise extended by agreement with the funding agency.

j. Release of Funds for New and Ongoing Studies

(i) Funds shall be disbursed from the Common Grant Account only upon receipt of the FHA 'Letter of Authorization to Conduct Research' for new studies and upon receipt of the certificate of annual renewal for ongoing studies from the FHA Research Office.
(ii) Grant recipients shall provide supporting documentation for all expenditures charged to their grant accounts. Such documentation shall include the following:

- for expenses related to salaries or stipends paid to research personnel: signed records regarding personnel paid from grant funds, including name, categories, salary levels, and length of time supported in each case, plus details of employee benefits charged and relevant calculations.
- salary forms shall be reviewed by the FHA Research Office to ensure compliance with funding agency requirements.

- for equipment and supplies: supplier invoices indicating details of purchases and prices paid, and;
- for internal expense allocations or shared expenditures: documentation indicating the exact charge being made, the method of calculation or attribution, and the grant recipient's authorization for those being assigned to the Common Grant Account.

(iii) Travel Expenses:

- Travel-related expenses shall be submitted as a separate claim for each trip.
- The affiliation with the grant recipient's research group shall be specified for claimants other than the grant recipient.
- The travel claim shall be countersigned by the grant recipient's administrative supervisor to confirm the relevance of the travel to the research being funded.
- The travel claim shall conform to the funding Agency requirements for information.

(iv) Record Keeping: All supporting documentation shall be kept for seven years after the expenditure has occurred.

k. Change in Eligibility

(i) The researcher shall notify the FHA Research office in the event that their eligibility for the grant changes during the tenure of the grant.
(ii) The FHA Research office shall notify the granting agency as soon as a grant recipient's eligibility status changes during the tenure of the grant.

l. Financial Reporting

(i) Monthly or quarterly statements of expenses and commitments shall be issued to principal investigators, as applicable.
(ii) A reconciliation of the commitments and payments made by the funding agency shall be made in accordance with the terms of the grant from each funding agency.
(iii) The Statement of Account shall be signed by the FHA Finance officer and the grant recipient.
(iv) The signed Statement of Account shall be retained on file.
(v) Other financial reporting shall be undertaken as requested.

m. Residual Balances

(i) Unspent balance of a grant at the end of the grant or extension period shall not be used for any other new purpose without prior authorization from the granting agency.

(ii) Remaining funds that are not approved for use during an extension period shall be returned to the funding agency along with a signed Statement of Account.

n. Review and Audit

(i) Five percent of transactions greater than $ 2501 shall be sampled on a periodic basis to ensure compliance with the guidelines of the funding agency.

(i) The FHA researcher who is the grantee shall make available all financial records for audit purposes when required, including review by external funding agencies.

(ii) All financial records shall be maintained for a period of seven years after the end date of the grant.

o. Controls to Prevent Over-expenditure

(i) A warning notice indicating low account balance shall be forwarded to the FHA researcher by FHA Finance and copied to FHA Research.

(ii) Cash advances are prohibited by FHA.

p. Withdrawal of Approval

(i) Approval of expenditures shall be withheld or withdrawn if, upon inquiry and investigation, there is evidence of research misconduct in that the grantee has contravened the funding agency regulations or FHA policies.

4.2.3 Industry Sponsored and Collaborative Research

a. Criteria For Negotiating Contracts With FHA

(i) FHA shall only be a party to contracts in which research is conducted by a FHA Researcher and/or in which there may be risk of liability when the research is conducted by an affiliated researcher.

b. Negotiation Of Clinical Trial Agreements

(i) The FHA Principal Investigator must ensure that the Clinical Trial Agreement [CTA/Contract] is sent to the FHA Research Office for review and negotiation.

(ii) The following information must also be provided with the CTA at the time of submission: sponsor contact information, principal investigator contact information, payee name and

address, the approved budget for the study and the Authorized Registry and Clinical Trial unique identifier for clinical trial registration.

(iii) The initial review and legal analysis will be completed within five business days.

(iv) All negotiations with the industry sponsor will be conducted by the designated FHA contract specialist on behalf of FHA and recommendations made to the sponsor/principal investigator.

(v) The final agreement shall be reviewed by the Director, FHA Research within one business day prior to execution.

(vi) The CTA will be signed by the VP or designate upon finalization of the terms of the agreement with the sponsor.

(vii) The CTA will be fully executed once signed by FHA, the sponsor, and the principal investigator for the study.

(viii) The Principal Investigator must ensure that a copy of the fully executed CTA is received by the FHA Research Office. It will be retained for twenty-five years.

c. Recovery Of Indirect Costs

a. The indirect costs of a research study shall normally be calculated as a percentage of the total direct costs of that project (i.e. the overhead rate). The Vice President Medicine may propose an alternative method of calculation should this need to be congruent with the policies of the contracting organization.

b. The VP in consultation with FHA Finance is authorized to set and adjust the rate in response to FHA requirements and changing circumstances.

c. Clinical trial sites for all industry funded studies shall be invoiced at the end of the first year of a study and at the end of every subsequent year of renewal by the Department of Evaluation and Research Services. The account ledger for a study shall be submitted to the Department of Evaluation and Research Services at the study close-out in order to reconcile amounts paid to date with the total amounts paid to the research site.

d. An annual report of the recovery of indirect costs shall be submitted to the VP Medicine.

4.3 General Procedures

a. Application for Affiliated FHA Researcher Status

(i) A non-FHA Researcher may make application to the FHA Research Office for this status. The application must include, at a minimum, a current curriculum vitae, explanation of why the applicant wishes a FHA affiliation, evidence of published research or evidence of completion of an academic doctoral degree, proposed areas of research interest, current affiliations and research activities if any.

(ii) The FHA Research Office shall undertake a review of the request and shall make a decision, taking into account risk to FHA and public benefit, and which will be reported in writing to the applicant.

(iii) Affiliated status may be conferred for a period of time stipulated by the VP, upon satisfactory completion of an agreement with the applicant's host institution.

b. Provision of Research-related Services By FHA Departments/Units

(i) FHA Principal Investigators carrying out research that requires FHA departments/units to provide research-related services must discuss and budget for the required services in consultation with the applicable department/unit. Each department/unit has the responsibility to ensure that funded services are provided on a cost recovery basis. Each department/unit involved in providing these services must set their own fee schedule.

(ii) Once the department/unit has agreed to provide the proposed service, the individual authorized by that department/unit must sign the "FHA Department Agreement for Providing Research-related Services" Form [**DAR** Form].

(iii) The FHA Principal Investigator must submit a copy of the DAR form with the applicable signatures authorizing the requested service to the FHA Research Office.

(iv) Upon receipt of all other applicable approvals [refer to authorization], the FHA Research Office will issue the letter of "Authorization To Conduct Research" to the Principal Investigator.

(v) The FHA Researcher must provide a copy of the signed FHA letter of "Authorization To Conduct Research" to the department/unit that has agreed to provide the required service before that service can be provided.

(vi) Upon receipt of the signed authorization letter, the department/unit can proceed to provide the required service.

(vii) Note that for services that require the release of personal information [including tissue] the applicable department must ensure that the FHA Principal Investigator signs a copy of the FHA Data Access Agreement Form or other applicable form that specifies how the confidentiality of the information released will be protected by the researcher. Refer to the FHA policy on "The Collection, Use and Disclosure of Personal Information for Research-related Purposes" for further details.

c. Purchase Of Equipment And Supplies

Purchases of equipment and supplies shall be made through the FHA Material Services.

d. Placement of Signed Consent Form for Research Participation in the Medical Record

A copy of the consent form signed by the research subject or their designated legal representative shall be put at the front of the medical record/chart while the research subject is an inpatient in FHA. If this is not possible, the signed consent form should be flagged by other means in the medical record/chart.

REFERENCES

Canadian Federal and Provincial Regulatory Requirements or Standards

(i) Federal Policy - TCPS

The 'Tri-council Policy Statement: Ethical Conduct for Research Involving Humans' (TCPS2) 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/

(ii) Health Canada Legislation

REB's that review clinical trial research AND researchers who conduct clinical trial research that is regulated by Health Canada must comply with the following regulatory requirements for research involving drugs, devices and natural health products:

Food And Drug Act: Regulations Amending The Food And Drug Regulations (1024 - Clinical Trials) For Clinical Trials For Drugs And Radiopharmaceuticals
Refer to:
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-286.html#h-274

Food And Drug Act: Medical Device Regulations – Part 3 Medical Devices For Investigational Testing Involving Human Subjects
Refer to:
http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-1.html

Food And Drug Act: Natural Health Products Regulations
Refer to:
http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-1.html

REB's who review clinical trial research and researchers who conduct clinical trial research that is regulated by Health Canada must also adhere to the International Conference on Harmonization Tripartite Guideline for Good Clinical Practice: Consolidated Guideline (1997) [ICH GCP].

Health Canada follows the ICH GCP's to determine whether or not good clinical practices are adhered to by researchers [i.e. qualified investigators] and research ethics boards during their inspections of clinical trials.

Refer to:
http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php

(iii) British Columbia Privacy Legislation

As a public body, the FHA, and the FHA REB and researchers under its jurisdiction 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.
Refer to: http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/96165_00

2. International Standards

(i) REB's that adhere to the ICH GCP and receive funds from United States government funding agency must adhere to the ethical principles contained in the 'Declaration of Helsinki' (1964) of the World Medical Association.
Refer to:
http://www.wma.net/en/30publications/10policies/b3/17c.pdf

(ii) Association of American Medical Colleges: Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials. January 6, 2006

3. United States Regulations

Researchers who conduct research funded either by the United States Department of Health and Human Services or other U.S. government agencies must comply with the following regulatory requirements for any of the funded research.

Department of Health and Human Services funded research regulated under 45 CFR 46.109 (e);
Refer to: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Other U.S. government funded research regulated under 21 CFR 56.110.

Refer to: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=56.110.

REBs that receive funds from United States government funding agency must adhere to the ethical principles contained in the 'Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research' (1979) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.

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Refer to:
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

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