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POLICY TITLE **RESEARCH**		**Catalogue Page Number** 5870
AUTHORIZATION Vice President, Patient Experience	**DATE APPROVED** June 2005	**CURRENT VERSION DATE** October 2021

PURPOSE

The purpose of this policy is to:

a) describe the authority and obligations under which research activities can be conducted at Fraser Health by Fraser Health researchers;

b) proscribe activities which breach generally acceptable standards of research conduct, and;

c) describe a process for handling allegations of research-related misconduct.

For the purposes of this policy, see Definitions

SCOPE

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

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

1.1. Criteria For Permitted Research

- The Fraser Health PI for any study conducted at a Fraser Health site or in connection with their Fraser Health responsibilities shall be directly affiliated with Fraser Health, by being either directly employed, having privileges, or by having met the requirements to obtain affiliated status. Academic researchers who wish to conduct research in Fraser Health must become affiliated with Fraser Health. Affiliated researchers shall have an academic appointment at a recognized academic institution or accredited healthcare organization. Refer to General Procedures.

- Students who are not Fraser Health 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 Fraser Health PI who has agreed to assume responsibility for the conduct of the study.
- The Fraser Health PI assumes responsibility for all co-investigators involved in their research study related activities, including development, conduct, analysis and reporting, whether these are Fraser Health Researchers or researchers not directly affiliated with Fraser Health (i.e. External).
- Research involving human participants shall be carried out according to the Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy
- 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 Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy.
- For greater clarity, Fraser Health 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 Fraser Health Research Ethics Board (FHREB).
- Fraser Health 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.

1.2. 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 Fraser Health 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 Fraser Health authorized personnel who have the authority to release non-confidential organizational information about Fraser Health 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 Fraser Health employees/privileged physicians as research participants or as researchers and which falls outside of their prescribed work time and / or broad fiduciary responsibilities to Fraser Health.

1.3. Research Requiring Executive Authorization

The following types of research, including but not restricted to, will not normally be carried out at Fraser Health:

- 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-Fraser Health affiliated researchers, and;
- research that is not in the public interest.

Special authorization shall be required from the Vice-President [VP[1]] to contemplate research projects that are outside the criteria for permitted research as defined in Criteria for Permitted Research.

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

1.4. Adherence to Standards of Integrity, Accountability and Responsibility

- Fraser Health 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 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.
- Fraser Health PIs 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.
- Fraser Health PI shall be financially responsible for all overspending on contracts or on grant accounts.
- Fraser Health PI conducting regulated clinical trials shall have standard operating procedures in place that adhere to the applicable legislative requirements and good clinical practices.

1.5. Signing Authority

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 Fraser Health Signing Authority - Policy.

1.6. Publication

- Results of research undertaken by Fraser Health researchers shall be made public and adhere to the publication policies of the granting agencies, where applicable.
  - Fraser Health researchers shall list the “Fraser Health Authority” as the professional affiliation or institution on all publications resulting from research conducted at Fraser Health.
  - All publications arising from grant funded research shall acknowledge the funding agency.
- The following qualifications pertain to research with *commercial interests such as industry sponsored research*.
  - 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 Fraser Health PI or to approve the publication in advance of publication by the Fraser Health PI, time for such protection or publication may be given provided that:
    - the Fraser Health PI 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.
    - if there is any change in the sponsor’s publication from the original report, the name of Fraser Health and the Fraser Health PI/co-investigator(s) shall not be used in connection with the publication without the written consent of Fraser Health and the Fraser Health PI/co-investigator, and;
    - publication of a thesis by a Fraser Health employee who is also a graduate student in an academic program shall not be delayed by such restriction.

- In exceptional circumstances, Fraser Health 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.

1.7. Monitoring of Research

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

1.8. Investigation of Research Misconduct

- Fraser Health 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.
- The Fraser Health Director, Research shall ensure that an investigative process is established. Refer to the Fraser Health Research Integrity - Policy for further detail.

1.9. Provision of Research-related Services

- Fraser Health departments/units may decline to provide research-related services to Fraser Health Researchers that are part of the FHREB 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 Provision of Research-related Services By Fraser Health Departments/Units
- 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.
- 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.
- Fraser Health departments/units providing research-related services shall submit an annual report of the provision of those services to the Fraser Health Director of the Department of Evaluation and Research Services

1.10. Recovery of Indirect Costs

- On the principle of cost recovery, Fraser Health shall recover indirect costs of research incurred to the organization by the conduct of industry-sponsored research or from, if allowable, government departments, and other granting agencies as well as through indirect program for affiliated academic institutions (i.e. Research Support Fund). The VP shall have the authority to waive this requirement when not allowed by the funding agency.
- The overhead rate for indirect costs for industry-funded research shall be a minimum rate of 40 percent, and the overhead rate for indirect costs for non-industry funded research (i.e. government or academic or non-for-profit) shall be a minimum rate of 15 percent. For more information, see Fraser Health Clinical Research Overhead Rates - Policy.

1.11. Compensation

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

1.12. Equipment

- 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 Fraser Health.
  - Proceeds from the sale of any grant-funded equipment or material shall be used for research-related purposes only.
  - Fraser Health 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.
- Equipment not in use by the grant recipient shall be made available for use by other Fraser Health personnel for their research.
  - Fraser Health may charge fees to these users should there be a requirement to recover direct costs incurred.
- A registry of research equipment shall be maintained by the Fraser Health Department of Evaluation and Research Services.

1.13. Acknowledgement of Contribution

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

1.14. Clinical Trial Registration

- Clinical trials which prospectively assign human participants 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 Fraser Health investigator sponsor with a registry that meets the requirements of the International Committee of Medical Journal Editors.
- 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 one clinical trials.

1.15. Participant Safety

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

1.16. Research Accounts

- In accordance with the financial requirements of agencies that have provided awards to Fraser Health researchers who are employees/privileged physicians, all research awards and funds received by Fraser Health employees/privileged physicians acting in their capacity as a Fraser Health PI 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 Fraser Health privileged physicians for the conduct of industry sponsored research, unless requested to do so by the physician PI for a study.
- Fraser Health PI shall abide by assigned responsibilities for their research cost centre(s).
- All Fraser Health PI shall notify the Department of Evaluation and Research Services of any proposals being submitted for funding to external agencies.
- Unspent grant funds shall be returned to the grant funder. If the funder does not require the return of the funds, the funds will become Department of Evaluation and Research Services revenue if after two years from study completion, the Fraser Health PI has not used those

funds. The only exception is if a letter is obtained from the funder restricting the funds for another specific purpose which also includes a timeline for use of the funds.

1.17. Reporting Institutional Conflicts of Interest

Fraser Health shall ensure that real, potential or perceived institutional conflicts of interest, as defined by the Fraser Health Conflict of Interest - Policy that may affect research are reported to the FHREB. The FHREB shall consider whether the institutional conflict of interest should be disclosed to prospective participants as part of the consent process for the applicable study.

1.18. Research Agreements

- Research that involves an external party(ies) shall require a written agreement that defines the obligations of Fraser Health and the external party(ies). This can apply to academic and other health authority based researchers and industry sponsors who require access to Fraser Health sites, patients and/or data to conduct research, industry sponsors that require a confidential review of a protocol, funding transferred to or from an academic institution, and installation of equipment for research purposes when funded externally.
- Agreements are not required when external researchers have prior consent from patients to obtain access to their medical record data (i.e. including tissue).

1.19. Records Retention

- Research records for regulated research are required to be held by the PI in a secure location for 25 years after study close-out.
- Research records for non-regulated research are required to be held by the PI in a secure location for five years after study close-out.
- Refer to the Fraser Health Records and Document Retention, Storage and Destruction - Policy - Appendix A Records Retention Schedule.

POLICY

Fraser Health 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, Fraser Health supports research activities carried out by Fraser Health researchers in the belief that research can improve the quality of care provided to the Fraser Health community[2]. The conduct of research within Fraser Health is considered a privilege and not a right, such that in undertaking research, Fraser Health and Fraser Health researchers are accountable for exercising due diligence in carrying out the legal, ethical and fiduciary requirements for the conduct of any research study. Fraser Health is committed to ensuring that Fraser Health researchers understand these obligations as well as their responsibility for carrying out the research according to scientific standards of reliability and validity. Fraser Health will also ensure that the research activities conducted by Fraser Health Researchers are fully transparent to the public, regulatory authorities and Fraser Health staff.

DEFINITIONS

Affiliated Researcher: An affiliated researcher is an individual who does not have a direct relationship with Fraser Health 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 VP.

[2] Fraser Health's Strategic Plan, October 2003, p. 2 and 37.

Authorization to Conduct Research Letter

- Letter issued by the Fraser Health Department of Evaluation and Research Services signifying that the appropriate approvals applicable to the named study have been obtained. These approvals include:
- Fraser Health Research Ethics Board Certificate of Initial Approval
- Fraser Health 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, Fraser Health, and PIs 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 PI who is deemed by the PI to carry out this role and who has some responsibility for the conduct of the trial. A co-investigator may be a Fraser Health Researcher or a researcher who is not affiliated with Fraser Health. The Fraser Health PI is responsible for the conduct of the co-investigator.

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. Fraser Health research contracts for industry sponsored clinical trials are tri-partite agreements between the industry-sponsor, Fraser Health, and the PI for that study. Contracts between Fraser Health and a collaborating partner are between Fraser Health 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 Fraser Health 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 Fraser Health may wish to consider

Department Agreement for Providing Research-related [DAR] Services Form: The DAR Form is available from the Fraser Health Research Department and must be used by Fraser Health researchers who require services from Fraser Health departments in order to carry out their research. The form must be completed with all applicable signatures by all Fraser Health researchers requiring services from Fraser Health departments and returned to the Fraser Health Department of Evaluation and Research Services before the Fraser Health '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 Fraser Health space.

External Researcher: An external researcher is a researcher who does not have an affiliation with Fraser Health and who is conducting research in a non-Fraser Health 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, Fraser Health, 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 PI, sponsor and Fraser Health 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 Fraser Health and the PI.
- Indemnification and insurance provisions shall be included in the agreements.
- Amendments to the protocol must be approved by the sponsor and the FHREB.
- Amendments to the clinical trial agreement must be approved by Fraser Health.

Independent Contractor: Refer to Fraser Health Independent consultant contracts

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, and 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 PI is the researcher who is deemed to have overall accountability for the research conducted at a Fraser Health site, despite who is the awardee of a grant for grant funded studies. The PI 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 PI must apply to Health Canada for approval, and therefore, is considered to be the Sponsor.**
- Ownership of any intellectual property vests in Fraser Health.
- 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 Fraser Health to the best of its ability.

Research Involving Human Participants:

- 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: System Optimization, Health Records, Laboratory 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.

Participant: A participant is an individual, living or dead, about who a research investigation is being conducted for a purpose other than the sole purpose of benefiting the participant, 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 for the purpose of this Policy.

PROCEDURE

2. Accountability and Obligations

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

2.1. Fraser Health[3]

- **Setting Expectations**
  Fraser Health shall be responsible for developing awareness and understanding among Fraser Health researchers and Fraser Health staff of the need for the highest standards of integrity, accountability and personal 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 Fraser Health researchers and staff.

- **Compliance with Legislation, Policies and Standards**
  Fraser Health complies with all applicable legislation, policies and standards for best practices that apply to the conduct of research by Fraser Health researchers and that at a minimum include:
  a) 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];
  b) policies, including the Canadian *Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans* [TCPS2], applicable granting agency policies, Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy and other Fraser Health policies that govern research activities.
  c) 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].

- **Authorization to Conduct Research**
  - Research is permitted to begin only when the Fraser Health Letter of Authorization to Conduct Research (LOA) is released to the Fraser Health PI by the Fraser Health Department of Evaluation and Research Services
  - The authorization shall be contingent upon receipt of the applicable approval documents by the Fraser Health Department of Evaluation and Research Services as listed in approvals (see Specific Requirements).
  - The authorization is required before Fraser Health Finance is permitted to release any funds to the Fraser Health researcher that are held in Fraser Health accounts.

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

- **Funded Research**
  - Fraser Health will follow generally accepted accounting practices [GAAP] regarding all financial transactions.
  - Disbursement of all Research Grants/Contracts shall be done under sound financial internal controls.
  - **Contracts**
    - Contracts which are binding on Fraser Health shall include terms and conditions that meet Fraser Health requirements for managing risk and are congruent with Fraser Health requirements relating to ethical review, privacy and confidentiality as governed by the Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy and Research - Collection, Use and Disclosure of Personal Information for Research Purposes - Policy.
  - **Grant Accounts and Uses**
    - Fraser Health may establish separate research accounts for sources of funding derived from grants awarded to Fraser Health PIs. Financial statements, if required by the granting agency shall be prepared by Fraser Health Finance according to their records. Fraser Health Finance shall retain original invoices/vouchers on file for audit purposes.
    - Research staff engaged as an independent contractor shall meet the requirements of Fraser Health 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 Fraser Health employees.
    - All honoraria, professional fees, salaries or payment for services shall be paid to individuals through the Fraser Health Accounting Services.
  - **Opening of Accounts for Awarded Grants**
    - The opening of a research account for a grant awarded study shall be authorized in writing by the Director, Fraser Health Department of Evaluation and Research Services with the applicable study specific LOA. The LOA shall be issued to Fraser Health Finance as confirmation that the applicable approvals are in place and that the award account can be opened.
  - **Use of Funds from Grant Accounts for Initial Study Year**
    - Fraser Health Finance shall only make awarded funds available for the first study year from the deferred grant account upon receipt of a copy of the Fraser Health LOA from the Fraser Health Department of Evaluation and Research Services.
    - Should FHREB 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.
  - **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, Department of Evaluation and Research Services that the ethical approval for the research study funded by that grant has been renewed and that a FHREB 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 Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy.

- **Research Misconduct – Refer to Fraser Health Research Integrity Policy**
  - **Investigation**
    Misconduct as defined in the Fraser Health 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.
  - **Suspension of Research Activities**
    Fraser Health shall order any approved research to be suspended immediately if there is any serious or continuing non-compliance with the Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy such that:
    - research is not being conducted in accordance with the current FHREB 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 FHREB'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.
  - **Reporting Noncompliance**
    Fraser Health shall promptly report any serious or continuing non-compliance with the Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy [4] and any suspension or termination of FHREB 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.
  - **Disciplinary Measures**
    PI 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.

- **Transparency**
  Fraser Health 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.

2.2. The Fraser Health Administrative Supervisor for the Researcher

- 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 Fraser Health 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.
- The administrative supervisor shall approve the initiation of any research in the department/unit under their supervision.

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

- The administrative supervisor shall fulfill their obligations as specified in the Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy

2.3. Fraser Health Researchers

- **Research Conduct**
  - All Fraser Health 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 Fraser Health The Ethical Conduct of Research and Other Studies Involving Human Participants - Policy.
  - All Fraser Health researchers abide by the Fraser Health 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.
  - All Fraser Health researchers shall ensure that all primary and secondary sources of information obtained for research purposes meets the requirements of the Fraser Health Policy on Research - Collection, Use and Disclosure of Personal Information for Research Purposes - Policy.
  - 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 Fraser Health site.
  - The Fraser Health PI for a research study shall be accountable for supervising the conduct of all co-investigators and research staff under their supervision to ensure compliance with this and other Fraser Health policies governing research. Specifically, the PI 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 Fraser Health Finance;
    - informing Fraser Health Department of Evaluation and Research Services 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 Fraser Health policies and procedures;

- notifying Fraser Health Department of Evaluation and Research Services 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 Fraser Health PI 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 Fraser Health site PI shall verify that the trial has been registered by the industry sponsor (or the overall PI if the study is run from another site).

- **Obtaining Required Approvals to Conduct Research**
  - The Fraser Health PI must seek to obtain the written permission of the senior administrator for their unit for any research-related study proposed by them or proposed by a student working under their 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.
  - The Fraser Health PI shall obtain all the necessary approvals for conducting research as listed under General Procedures and submit these to the Fraser Health Department of Evaluation and Research Services in order to obtain the Fraser Health LOA.
  - The Fraser Health PI shall not permit any research-related activities to begin until the Fraser Health LOA for the applicable study has been received from the Fraser Health Department of Evaluation and Research Services.

- **Use of Research Funding**
  - All Fraser Health 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 Fraser Health Finance and any other Fraser Health departments that are involved in the administration of the funds, and with the requirement for annual ethical approval.
  - Requests for new accounts or amended accounts, such as budget increases to existing accounts, must be made in writing.

- **Ownership of Results and Publication**
  - Fraser Health 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.
  - The Fraser Health PI shall endeavour to publish the results of the research, subject to qualifications listed in 1.6 Publication.
  - The Fraser Health PI 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.

- The Fraser Health PI 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.
- 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.
- The Fraser Health PI 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
- All researchers shall disclose any potential intellectual property arising from their research.

3. Specific Requirements

3.1. Approvals Required For Fraser Health Letter of 'Authorization to Conduct Research'

The Fraser Health PI for a study must ensure that the following approvals have been completed and/or submitted to the Fraser Health Department of Evaluation and Research Services **before** research-related procedures are initiated.

Mandatory approval for **all** types of research studies:
- Fraser Health 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 Fraser Health *Department Agreement For Providing Research-related Services'* Form [DAR] for services required from Fraser Health departments/units (refer to 4.2).

Upon receipt of the applicable approvals, the Fraser Health Department of Evaluation and Research Servicesshall sign and release a LOA to the PI. This letter is required before any research-related can begin.

3.2. Grant Funded Research

The following procedures apply to:

a) every new application for external funding for research-related activities;
b) requests for renewal/supplementation of funding to existing projects, and;
c) letters of intent.

- **Internal Review Of Applications For Funding**
  - Internal review by the Department of Evaluation and Research Services is required before all new applications for funding are approved for signature by Fraser Health in order to confirm the PI'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 Fraser Health approvals is/has been implemented.
  - The PI must submit one copy of the proposed research for internal review prior to submitting the application to a granting agency.

- The internal review and distribution of comments to the PI will be coordinated through the Fraser Health Department of Evaluation and Research Services.

- **Required Signatures For Applications**
  - 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, VP or designate.
  - The PI must ensure that the required signatures are obtained prior to submitting the application to the granting agency.
  - 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 Fraser Health authorities;
    - if an award is made, Fraser Health 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, Fraser Health will not release funding to the awardee until all award conditions of the granting agency and the Fraser Health 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 Fraser Health Department of Evaluation and Research Services and the granting agency if there is any change in their status that affects the award.

- **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 Fraser Health requirements.

- **Notification of Research Awards Received**
  - All Fraser Health researchers who receive awards, either in the form of grants or unsolicited donations, shall notify the Fraser Health Department of Evaluation and Research Services 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.

- **Review of Awardee Eligibility**
  - Upon receipt of the award notice, the Fraser Health Department of Evaluation and Research Services shall review the status of the awardee and the certification/approval status of the study to confirm eligibility to receive the award.

- **Receipt of Awarded Grant Funds**
  - All cheques awarded to Fraser Health Researchers must be made payable to the "Fraser Health Authority".
  - Cheques received by Fraser Health awardees or departments must be forwarded to the Fraser Health Department of Evaluation and Research Services for deposit to the appropriate Fraser Health Research account.
  - Fraser Health personnel shall not accept personal cheques for research support.

- **Research Accounts**
  - 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.

- **Expenditure Authorization**
  - 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 PI.
  - All claims shall have the grant recipient's or delegate's signature.
  - 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 Fraser Health.
  - 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.

- **Release of Funds for New and Ongoing Studies**
  - Funds shall be disbursed only upon receipt of the Fraser Health LOA for new studies and upon receipt of the certificate of annual renewal for ongoing studies from the Fraser Health Department of Evaluation and Research Services
  - 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;
    - Meditech shall be reviewed by the Fraser Health Department of Evaluation and Research Services to review who receives salary from the research grant;
    - 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
  - **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 or the Fraser Health Department of Evaluation and Research Services signatory to confirm the relevance of the travel to the research being funded.
        - The travel claim shall conform to the funding Agency requirements for information.
    - **Record Keeping**:
        - All supporting documentation shall be kept for seven years after the expenditure has occurred.

- **Change in Eligibility**
    - The researcher shall notify the Fraser Health Department of Evaluation and Research Services in the event that their eligibility for the grant changes during the tenure of the grant.
    - The Fraser Health Department of Evaluation and Research Services shall notify the granting agency as soon as a grant recipient's eligibility status changes during the tenure of the grant.

- **Financial Reporting**
    - Monthly or quarterly statements of expenses and commitments shall be issued to PIs, as applicable.
    - 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.
    - The Statement of Account shall be signed by the Fraser Health Finance officer and the grant recipient.
    - The signed Statement of Account shall be retained on file.
    - Other financial reporting shall be undertaken as requested.

- **Residual Balances**
    - 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.
    - 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.
    - Unspent balances in relation to an industry sponsored contract will not be returned to the sponsor unless negotiated in the contract

- **Review and Audit**
    - Five percent of transactions greater than $2501 shall be sampled on a periodic basis to ensure compliance with the guidelines of the funding agency.
    - The Fraser Health researcher who is the grantee shall make available all financial records for audit purposes when required, including review by external funding agencies.
    - All financial records shall be maintained for a period of seven years following the date of expenditure.

- **Controls to Prevent Over-expenditure**
  - A warning notice indicating low account balance shall be forwarded to the Fraser Health researcher by Fraser Health Finance and copied to Fraser Health Department of Evaluation and Research Services.
  - Cash advances, with the exception of travel, are prohibited by Fraser Health.

- **Withdrawal of Approval**
  - 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 Fraser Health policies.

3.3. Industry Sponsored and Collaborative Research

- **Criteria For Negotiating Agreements With Fraser Health**
  - Fraser Health shall only be a party to contracts in which research is conducted by a Fraser Health Researcher and/or in which there may be risk of liability when the research is conducted by an affiliated researcher.
  - Fraser Health shall generate the appropriate agreement for affiliated researchers in consultation with the academic institution in order to ensure Fraser Health requirements are met.
  - Fraser Health shall review research agreements generated by, for example, an industry sponsor, to ensure Fraser Health requirements are met.

- **Negotiation Of Clinical Trial Agreements**
  - The Fraser Health PI must ensure that the Clinical Trial Agreement [CTA/Contract] is sent to the Fraser Health Department of Evaluation and Research Servicesfor review and negotiation.
  - The following information must also be provided with the CTA at the time of submission: sponsor contact information, PI 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.
  - The initial review and legal analysis will be completed within ten business days.
  - All negotiations with the industry sponsor will be conducted by the designated Fraser Health contract specialist on behalf of Fraser Health and recommendations made to the sponsor/PI.
  - The final agreement shall be reviewed by the Manager, Clinical Trials and Business Development within one business day prior to execution.
  - The CTA will be signed by the Director, Executive Director, VP, or designate upon finalization of the terms of the agreement with the sponsor.
  - The CTA will be fully executed once signed by Fraser Health, the sponsor, and the PI for the study.
  - The PI must ensure that a copy of the fully executed CTA is received by the Fraser Health Department of Evaluation and Research Services. It will be retained for twenty-five years from the date of study closure.

- **Recovery Of Indirect Costs**
  - 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 VP may propose an

alternative method of calculation should this need to be congruent with the policies of the contracting organization.

- The VP in consultation with Fraser Health Finance is authorized to set and adjust the rate in response to Fraser Health requirements and changing circumstances.
- Collection of indirect costs via established overhead rates will managed and allocated by the Department of Evaluation and Research Services to support research infrastructure and activities within Fraser Health.
- An annual report of the recovery of indirect costs shall be submitted to the VP.

4. General Procedures

4.1. Application for Affiliated Fraser Health Researcher Status

- A non-Fraser Health Researcher may make application to the Fraser Health Department of Evaluation and Research Servicesfor this status. The application must include, at a minimum, a current curriculum vitae, explanation of why the applicant wishes a Fraser Health 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.
- The Fraser Health Department of Evaluation and Research Services shall undertake a review of the request and shall make a decision, taking into account risk to Fraser Health and public benefit, and which will be reported in writing to the applicant.
- 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.

4.2. Provision of Research-related Services By Fraser Health Departments/Units

- Fraser Health PIs carrying out research that requires Fraser Health 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.
- Once the department/unit has agreed to provide the proposed service, the individual authorized by that department/unit must sign the *Department Agreement for Providing Research-related Services* Form [DAR Form].
- The Fraser Health PI must submit a copy of the DAR form with the applicable signatures authorizing the requested service to the Fraser Health Department of Evaluation and Research Services.
- Upon receipt of all other applicable approvals [refer to authorization], the Fraser Health Research Office will issue the LOA to the PI
- The Fraser Health Researcher must provide a copy of the signed Fraser Health LOA to the department/unit that has agreed to provide the required service before that service can be provided.
- Upon receipt of the signed authorization letter, the department/unit can proceed to provide the required service.
- Note that for services that require the release of personal information [including tissue] the applicable department must ensure that the Fraser Health PI signs a copy of the Fraser Health 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

Fraser Health Research - Collection, Use and Disclosure of Personal Information for Research Purposes - Policy for further details.

4.3. Purchase Of Equipment And Supplies

- Purchases of equipment and supplies shall be made through the required Fraser Health process.

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

- A copy of the consent form signed by the research participant or their designated legal representative shall be put at the front of the medical record/chart while the research subject is an inpatient in Fraser Health. 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:

a. Federal Policy – TCPS2

The *Tri-council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) 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/.
Note that the Fraser Health policy supersedes the TCPS2 definition of participant.

b. Health Canada Legislation

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

REBs 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

c. British Columbia Privacy Legislation

As a public body, Fraser Health, and the FHREB 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

International Standards

a. REBs 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

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

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

FRASER HEALTH CORPORATE RESEARCH-RELATED POLICIES

- Clarification of Ethical Review Requirements for Studies Involving Quality Assurance/Improvement, Program Evaluation, Operational Review and Product Evaluation
- Research - Policy
- The Collection, Use and Disclosure of Personal Information for Research-related Purposes Policy
- Research Integrity - Policy
- Whistleblower Protection - Policy
- Confidentiality and Security of Personal Information - Policy
- Conflict of Interest - Policy
- Records and Document Retention, Storage and Destruction - Policy see Appendix A

DATE(S) REVISED / REVIEWED SUMMARY

Version	Date	Comments / Changes
1.0	June 2005	Initial policy
2.0	January 2007	Addition of: • reference to the FH Research Integrity - Policy. • requirements for the purchase of equipment from a grant funding agency. • requirement to acknowledge financial contribution from external funders in any type of publication. • requirement for clinical trial registration for clinical trial research. • requirement for retention and visibility of research subjects' signed consent forms in the medical record. • requirement for review of grant awardee eligibility. • requirement regarding set up of research accounts for grant awardees. • requirement for expenditure authorization for research grants. • requirement for release of funds for funded new and ongoing research. • notification requirement for change in researcher eligibility for research awards • financial reporting requirements for grant funded research. • requirement for return of residual funds to the granting agency. • requirement for review and audit of financial transactions. • requirement for controls to prevent over-expenditure by FH researchers. • conditions for withdrawal of approval of financial expenditures.
3.0	October 2009	Change in overhead rate for industry funded research.
4.0	November 2010	Change in overhead rate for industry funded research.
5.0	May 2012	• Additional specifications for the scope of the policy. • Addition of criterion for permitted research regarding affiliated researchers. • Addition of criteria for types of studies, i.e. not research, excluded from the scope of the policy. • Revision of article to comply with FH policy regarding signing authority. • Addition of requirement to acknowledge the FHA and the funding agency in publications. • Addition of specification for research accounts. • Addition of requirement to report institutional conflicts of interest related to research.
6.0	January 2013	• Format; links updated • Clarification regarding Lower Mainland Consolidation FH and non-FH employees who conduct research • Addition of clarification regarding criteria for permitted research in FH. • Clarification that FH may publish research results. • Clarification added regarding adherence to the granting agency requirements for publication. • Clarification regarding uses of equipment subject to funding agency agreements • Requirement regarding adherence by researchers to assigned responsibilities for cost centres for funded research. • Clarification regarding relationship between institutional conflicts of interest

		regarding research and FH Corporate Conflict of Interest - Policy • Definitions: Data Access Agreement – Addition of Fraser Health Privacy requirement. • Reference to FH Corporate Conflict of Interest Policy added.
7.0	August 2017	• Clarification of scope as it applies to non-FH researchers who have research affiliation agreements with FH. • 'Subjects' changed to 'participants' throughout in order to be consistent with TCPS2 2014. • FH/FHA replaced with FH throughout in order to be consistent with current FH Communications standards. • Requirement for standard operating procedures added for regulated clinical trials. • Indirect Costs – Clarification regarding recovery of these costs. • Research Accounts – Clarification about the requirements for return of unspent grant funds. • Research Agreements – This section was added to clarify requirements for research agreements. • Record Keeping – Procedure was updated to address FH Record Retention Schedule and to clarify retention guidelines for regulated versus non-regulated studies. • FH Opening of Accounts for Awarded Grants revised. • Procedure - Copies of Agreements deleted. • Procedure - Release of Funds for New and Ongoing Studies clarification for use of Meditech and travel expenses. • Procedure Industry Sponsored and Collaborative Research – Clarification added for other types of agreements.
8.0	September 2021	• Change in VP responsible for Research; • Change in overhead rate for industry funded research; • Addition of overhead rate for non-industry funded research; • Direction to new policy "Clinical Research Overhead Rates"