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CORPORATE POLICY, STANDARDS and PROCEDURE

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POLICY TITLE **THE ETHICAL CONDUCT OF RESEARCH AND OTHER STUDIES INVOLVING HUMAN SUBJECTS**		**NUMBER**
AUTHORIZATION Vice President, Medicine	**DATE APPROVED** April 2005	**CURRENT VERSION DATE** January 2014

DATE(S) REVISED / REVIEWED SUMMARY [1]

Version	Date	Comments / Changes
1.0	April 2005	Initial Policy
2.0	January 2007	Procedure 4.2.2 d) - Clarification added regarding requirement for majority vote.
2.0	January 2007	Procedure 4.6 - Procedure added for the conduct of an appeal process.
2.0	June 2007	Policy Article 3.5 - Addition of requirements for reporting Relationships added and deletion of original Article 3.5.
3.0	June 2007	Procedures 4.1.1 d) - Clarified that that the researcher may request an appeal of a FHREB decision.
3.0	June 2007	Procedure 4.1.2 a) i) - Original requirement to report to the Vice President deleted.
3.0	June 2007	Procedure 4.1.2 i) vi) - Procedure added for review of research involving emergency health services.
3.0	June 2007	Procedure 4.1.4 b) i) - Clarification added that the current Tri-council Policy must be used.
4.0	May 2012	Policy Article 2.2 - Clarification regarding use of human biological materials for research.
4.0	May 2012	Policy Article 3.1 - Clarification regarding requirements for FHREB review with respect to renewal of research.
4.0	May 2012	Policy Article 3.2 - Clarification of scope of FHREB jurisdiction.
4.0	May 2012	Policy Article 3.3 – Clarification regarding types of studies not requiring review by the FHA Research Ethics Board.
4.0	May 2012	Policy Article 3.4 – New article regarding FHA Research Ethics Board reporting relationship to the FHA Corporate Board of Directors.
4.0	May	Policy Article 3.5 – New article regarding appointment of the FHA

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	2012	Research Ethics Board by the Vice President Medicine.
4.0	May 2012	Procedure 4.1.2 b) vi) - Procedure added regarding appointment of Director, Department of Evaluation and Research Services as ex officio FHREB member.
4.0	May 2012	Procedure 4.1.2 c) - Clarification regarding quorum.
4.0	May 2012	Procedure 4.1.4 b) i) - Requirement added for declaration of conflicts of interest, including institutional conflicts, by FHA researchers.
5.0	January 2014	Format; links updated.
5.0	January 2014	Policy Article 3.1 - Clarifies requirement for review of research conducted by FHA employees who, as part of Lower Mainland Consolidation, conduct research at a non-FHA site involving non-FHA patients.
5.0	January 2014	Policy Article 3.2 a iii) - Clarifies scope of FHREB review with respect to FHA employees who are part of Lower Mainland Consolidation.
5.0	January 2014	Policy Article 3.2 c) – Clarifies FHA responsibility for research involving FHA employees/privileged physicians outside of their FHA responsibilities.
5.0	January 2014	Policy Article 3.2 d) – New policy article that clarifies FHA's right to require appropriate approval processes be followed in order to grant access to information for research purposes
5.0	January 2014	Policy Article 3.2 e) – New policy article that limits FHA's responsibility for any independent research if not approved by FHA.

1.0 INTENT / PURPOSE

Fraser Health [FHA] [2] recognizes that the participation of human **subjects** is indispensable in order to conduct research that will benefit society as a whole.

This policy is intended to create a research environment within Fraser Health in which the protection of human subjects is considered a priority by:

[2] Fraser Health, FHA or FH may be used throughout this policy and denote the Fraser Health Authority

- ensuring that responsibilities for reviewing and conducting research are discharged according to the highest ethical standards;
- promoting awareness of research ethics among FHA staff;
- establishing an independent research ethics review process, and;
- putting into place the mechanisms for the protection of human subjects in ongoing research, including the monitoring of ongoing research.

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

2.0 POLICY

Where, in the course of research or other studies that are to be carried out under the aegis of the FHA, procedures involve human subjects, it is the primary concern of the FHA that the rights, dignity, welfare, safety and integrity of the subject are respected and protected throughout the entire research process to the conclusion of the research study. To this end, the ethics review process is independent of FHA's other administrative decision-making processes that also impact the conduct of research at FHA sites. The Ethics Review Process uses fair methods, standards and procedures for reviewing research studies.[3]

2.1 Statement Of Ethical Principles

It is expected that the procedures followed in studies that involve human subjects are acceptable on moral grounds and abide by the following fundamental ethical principles for subject-centered research:

- the informed consent of subjects to participate is given voluntarily based upon a thorough consent process and may be withdrawn at any time, for any reason, and by any communication means;
- subjects, with particular attention to vulnerable subjects, are protected against abuse, exploitation and discrimination;

[3] Refer to the FHA 'Research Policy' for details on the institutional requirements that researchers must adhere to in parallel with the requirement for ethics review.

- selection of subjects is fair and does not discriminate against individuals and groups who may benefit from advances in research;
- foreseeable harms will not outweigh the anticipated benefits;
- research subjects will not be subjected to unnecessary risks of harm, and their participation in research is essential to achieve scientifically and socially important aims that cannot be realized without the participation of human subjects;
- standards for privacy and confidentiality are observed with respect to access, control and dissemination of personal information including contact information;
- actual and potential conflicts of interest of researchers and individuals involved in the review process are made known and dealt with appropriately.

2.2 Definition Of Research And Other Studies Involving Human Subjects

Research involving human subjects is defined as any systematic investigation (including pilot studies, exploratory studies, and academic course work assignments) designed to contribute to generalizable knowledge. Generalizable knowledge consists of facts, theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. Research includes:

- obtaining data about a living individual through intervention (e.g. a medical procedure) or interaction (e.g. an interview) with the individual, or the obtaining of private personal information about the individual, 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.

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3.0 POLICY

3.1 Requirement For Ethical Review And Approval

a. No research or other study involving human subjects, as defined above Research, shall be undertaken by anyone acting in their FHA capacity, nor may FHA facilities or services be used, nor may funds for such purposes be accepted, nor accounts opened by FHA Financial Services and funds released unless the proposed research has been submitted for initial ethical review and received formal written ethical approval by the FHA Research Ethics Board [REB] before the research proposed is initiated, unless under Lower Mainland Consolidation, the FHA employee is conducting research at a non-FHA site involving research subjects from the non-FHA site that are not FHA patients, clients or residents and that site's Research Ethics Board has reviewed and approved the research. Under such circumstances, the FHREB will accept the certificate of ethical approval from the non-FHA site.

b. The researcher who is the FHA principal investigator for the study must receive the FHA REB Certificate of Initial Approval for the research study in conjunction with the FHA Letter of Authorization to Conduct Research before the proposed research can begin.

c. Any amendments to the proposed research or new information that could affect adversely the safety of the subjects or the conduct of the trial, other than those amendments implemented to eliminate immediate hazards to study subjects, shall be submitted to the FHA REB for review and approval.

- The amendment can only be implemented once it has been approved and the Certificate of Approval for the Amendment has been received by the researcher who is the FHA principal investigator for the study,

d. All research studies that are continuing to collect data for the purposes of conducting the research shall be submitted to the FHA REB for annual approval before the expiry date of the initial certificate of ethical approval or the current certificate of annual approval whichever is applicable. The collection of data includes that obtained from currently enrolled research

subjects, secondary data sources, the retrieval of tissue from tissue banks, and the participation of new subjects after the expiry date.

- The participation of new subjects, collection of data from secondary sources and retrieval of tissue from tissue banks shall only continue once the Certificate of Approval for the Annual Renewal has been received by the researcher who is the FHA principal investigator for the study.

- Renewal of previously approved studies is not required if all data/tissue collection is complete and data/tissue analysis only is being undertaken.

3.2 Scope Of FHA REB Jurisdiction

a. The FHA REB reviews all human subjects research, as defined above Research, regardless of the type of funding [i.e. grants, contracts, grants-in-aid or gifts, budgeted funds of the FHA, or not funded], if one or more of the following apply:

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 using any FHA property, including data, medical records or tissue, facility, and/or involving any FHA patients, clients, residents or FHA employees/privileged physicians 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, unless under Lower Mainland Consolidation, the FHA employee is conducting research at another site and the research protocol is reviewed and approved by that site's Research Ethics Board, [refer to 3.1 and see 3.3 below], or;
iv. the research is under the direction of and conducted 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.

b. Any researcher deemed to be the principal investigator for a study conducted at FHA shall be affiliated with FHA.

c. Research that 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 Fraser Health and which does not access any patient health records or any administrative records that is not already in the public domain shall not be reviewed by the FHA REB.

d. 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 FHA REB.

e. 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.

3.3 Types Of Studies Normally Excluded From Ethical Review

Studies that are excluded from the definition of 'research' and are therefore not subject to ethical review 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;

Notwithstanding these exclusions, any study that includes an element of research may require ethics review.

3.4 Reporting Relationship

(i) The FHA REB shall report to the FHA Board of Directors and provide an annual report of its activities and other matters as requested. The annual report once accepted by the FHA Board of Directors will be placed in the public domain.

3.5 REB Appointment

The Vice President appoints the FHA REB appointment and provides the REB with the administrative and financial support and independence to execute its mandate.

DEFINITIONS

a. Anonymous

Anonymous data or tissue is anonymous due either to the absence of tags or records [i.e. the source has never been identifiable]. This means that no member of the research group knows the subject identity and that identification of subjects is NOT possible by any means or by the information obtained from subjects.

b. Anonymized

Anonymized data/tissue was originally identified but has been permanently stripped of all possible identifiers and therefore is no longer identifiable.

c. Assent

Assent is an incompetent subject's agreement to participate in research after an adequate explanation has been provided. Assent shall not be assumed simply because the incompetent subject does not object. Refer to FHAA REB Policies

d. Canadian Federal and Provincial Regulatory Requirements or Standards

(i) Federal Policy - TCPS

The 'Tri-council Policy Statement: Ethical Conduct for Research Involving Humans' provides the Canadian framework for ethical review of research involving human subjects.

- Refer to: http://www.pre.ethics.gc.ca/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://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php

- 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].

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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

e. 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.

f. Confidentiality

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

g. Decisions of the REB

Final Approval No concerns with the protocol, the consent form(s) or any other research related documentation.
The investigator has ethical approval to proceed with the study.

Minor Modifications Questions remain about the protocol, itself, or revisions are

Required - Response can be reviewed by a co-Chair	required to the consent form(s)/other documentation. This decision does not indicate permission to commence the study.
Major Modifications Required – Deferral Response must be submitted to and reviewed by the full Board.	Major methodological or ethical questions exist and/or documentation may not be complete. The investigator may be invited to the next meeting to provide an opportunity to reply to the review before the REB makes a final decision.
Not Approved	Major methodological or ethical questions continue to exist. The research is not approved and may not be conducted in its current form. No further consideration of the project in its current form will be undertaken.

h. Identifiable

Identifiable data/tissue can be linked to a specific individual by way of an identifying tag or identifier. Usually the key to linking the data to the subject identity is retained by a specified custodian.

i. Incompetent

An incompetent subject is someone who is not qualified to give or who is incapable of giving informed consent according to the researcher's assessment of their 'competence'. Refer to FHA REB Policies

j. Informed Consent

Informed consent is the agreement of a subject/legal representative to take part in research after the procedures, costs, and potential risk and benefits have been explained in a manner that the subject can understand.

k. International Standards

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

l. 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.

REB's 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://ohsr.od.nih.gov/guidelines/belmont.html

m. Minimal Risk

Minimal Risk is defined in the TCPS as: "...if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk" [TCPS C1].

Categories of research that may qualify for delegated review include the following:

- Research employing only survey, interview, oral history, focus group, or human factors evaluation methodologies;

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- Research involving materials (data, documents, medical records, or banked anonymous tissue specimens) that were originally collected for non-research purposes;
- Collection of data from voice, video, digital or image recordings previously made for research purposes;
- Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour).
- Research involving moderate exercise interventions using normal healthy volunteers
- Research involving collections of hair, nail clippings, deciduous teeth, excreta, salivary secretions, additional swabs, other external secretions that have been collected in a non-invasive manner and that may also be collected as part of routine clinical care in addition to placenta or amniotic fluid collected as a consequence of normal labour and delivery;
- Research involving data recorded using non-invasive procedures routinely employed in clinical practice (e.g. EEG or EKG);
- Research involving blood samples collected by venipuncture and that may also be collected as part of routine clinical care but are not used for either banking or genetic testing;
- Research involving other clinical non-invasive data that may be collected as part of routine clinical care and used for observational research.

n. Principal Investigator

The principal investigator is the FHA researcher who is deemed to have overall accountability for the research conducted at a FHA site.

o. Protocol Deviations/Violations

A protocol deviation is defined as an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current approved research protocol, consent document or study addenda. Examples of protocol deviations that require review by the FHA REB include:

i) changes in procedures initiated to eliminate immediate hazards to study subjects;
ii) enrolment of subjects outside protocol inclusion/exclusion criteria, whether agreed to or not by the sponsor;

iii) medication/intervention errors [i.e. incorrect drug/intervention, incorrect dosage of the drug];
iv) inadvertent deviation in specific research intervention procedures or timing of the research intervention which could impact upon the safety or efficacy of the study-related intervention or upon the experimental design [n.b. this would not include appointment deviations usually];
v) breach of confidentiality or privacy whereby confidential information about a subject is revealed in inappropriate settings, or to persons without a need to know, or by data exposure (computer security breach, documents left unsecured), and;
vi) significant deviation from the consenting process.

p. Serious and Unexpected Adverse Events

Serious Adverse Event means an event that is:

- fatal
- life-threatening
- persistent or significantly disabling or incapacitating
- inpatient hospitalization or prolongation of hospitalization
- congenital anomaly or defect and/or
- a significant medical incident (considered to be a serious study related event because, based upon appropriate medical judgment, it may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.)

Unanticipated Adverse Event means an event that results from a study intervention and was not expected or anticipated from prior experience. This includes expected events that occur with greater frequency or severity than predicted from prior experience.

q. 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.

4.0 PROCEDURE

4.1 Accountability And Obligations

To ensure that the obligations of FHAA 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

a. The Ethical Framework

(i) Fraser Health provides the governance and administrative structure for the review, approval and monitoring of all research involving human subjects and ensures that this is carried out in accordance with the most current version of the *'Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans'* (1998) [TCPS] of the Canadian Institutes of Health Research, the National Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada. The application of these requirements concerning the ethical conduct of research involving human subjects is also consistent with the ethical principles in the '*Declaration of Helsinki*' (2000) of the World Medical Association and the *'Belmont Report'* (1979) of the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (International Standards).

(ii) Where applicable to specific research, the ethical review shall also be conducted in accordance with other relevant national and provincial regulatory requirements Canadian or standards and/or international regulations and standards United States, as describe below under Definitions.

b. Education

(i) FHA ensures that researchers and their staff receive appropriate training in the skills necessary for the ethical conduct of such research. This includes awareness of policies and other relevant standards (e.g. legal, professional, and institutional) pertinent to the particular area of research.

c. Appeal Of REB Decision To Not Approve A Research Study

(i) FHA cannot override negative decisions of the FHA REB [e.g. requests for modifications] made throughout the ethical review process as these decisions of the REB are final. However if the REB has made a final decision to not approve a study, the researcher may make a request in writing to the VP for review of that decision by the designated appeal board for the FHA REB.

d. Authority To Over-Ride REB Approval Decisions

(i) The VP shall have the authority to override any approval decisions of the FHA REB in order to restrict types of research from being conducted within FHA if the research is outside the interests of FHA.

e. Suspension Or Termination Of Approval Of Research

(i) FHA can order any approved research to be stopped 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"* or the FHA "Research Policy" or any other FHA policy that applies to FHA employees and privileged physicians who are conducting research, 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 [refer to 3.6.2 I Suspension], 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.

f. Reporting Noncompliance

(i) 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"* [4] 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 Human Research Protections.

4.1.2 THE FHA REB

a. Composition, Appointment And Term Of The FHA REB

(i) REB members shall lodge with the Vice President their curriculum vitae/resume upon appointment and an annual statement of conflict of interest and in order to comply with the FHA Conflict of Interest policy.

(ii) The REB comprises the following types of members including both men and women, of whom a majority of members are Canadian citizens or permanent residents under the Immigration Act.

- two members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline;[5]
- one member knowledgeable in ethics;
- one member knowledgeable in the relevant law;
- one member whose primary experience and expertise are in a nonscientific discipline, and;
- one member with no affiliation with FHA, but who is recruited from communities within FHA.

(iii) Appointments to the FHA REB are made by the FHA VP in consultation with the applicable directors of FHA departments and divisions. The initial appointment is for a three year term,

[4] This includes Canadian regulations governing clinical trial research and United States federal regulations governing U.S. government funded research.
[5] Natural health product research shall be reviewed by a member with expertise in natural health products.

with the possibility of a renewal for a further three-year term. Terms of individual members shall be staggered to ensure that there is a mechanism for maintaining continuity of the FHA REB expertise.

(iv) The VP shall appoint the Chair/Co-Chairs of the FHA REB, normally from amongst the membership of the FHA REB, for a three-year term as Chair/Co-Chair renewable for a further three years.

(v) On an annual basis, the VP may appoint an Associate Chair of the FHA REB, to chair the REB meetings and make decisions in the absence of the Chair/Co-Chair.

(vi) The VP shall appoint the Director, Department of Evaluation and Research Services as an 'ex-officio' member to ensure that the REB is informed of FHA policy and other regulatory requirements that affect the conduct of research in the health authority. The ex-officio member may provide comment on the REB deliberations but shall not participate in the final decisions approved by the board.

b. Quorum

(i) Meetings of the REB shall comprise a face to face meeting of a minimum of five members such that there is always representation from the community member and from the members knowledgeable in ethics and the relevant law. When there is less than full attendance, decisions requiring full review shall be adopted only when the members in attendance at the meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

c. Responsibilities And Functions

(i) The FHA REB performs its functions according to written standard operating procedures. For details refer to the "FHA REB Standard Operating Procedures" (SOPs) under References.

(ii) The FHA REB considers applications for ethical review of new studies, for amendments to previously approved studies and for annual renewal of previously approved studies. In addition, the REB reviews all information related to the safety of subjects, including but not restricted to serious and unexpected adverse event reports **(SAEs)** and protocol deviations.

(iii) The FHA REB determines whether research studies submitted for review are acceptable on ethical, scientific and scholarly grounds and in so doing whether the research complies with the '*Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects'* and, where applicable, national and provincial regulatory requirements or standards and/or international regulatory requirements and standards, as defined below.

d. Requirement For Informed Consent And Assent

(i) The FHA REB requires that informed consent be sought from each prospective subject or that subject's legally authorized representative for participation in prospective research. Refer to the 'FHA REB Consent Form Template' for specific details on consent form requirements. See References.

(ii) The FHA REB requires that assent be sought from each prospective subject who is capable of assenting but who is not competent to consent on his/her behalf. Refer to the 'FHA REB Assent Form Template' for specific details on consent form requirements. See References.

(iii) The FHA REB requires that consent/assent when obtained is appropriately documented and dated by the individual obtaining the consent.

e. Studies Not Requiring Consent/Assent

(i) The FHA REB does not require that consent/assent be sought when the research to be conducted involves collecting data from secondary sources of previously collected data (e.g. medical records) without any direct subject contact OR if collecting tissue from tissue banks that hold anonymized [i.e. non-identifiable] or anonymous tissue.

f. Proportionate Approach To Ethics Assessment

(i) The FHA REB uses a "proportionate" approach to review new proposed and ongoing research studies. Research that does not meet the definition of 'minimal risk', as defined below, by virtue of either the invasiveness of the research and/or the potential for more harm to subjects receives full board review.

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(ii) Submissions that meet the definition of minimal risk in that the potential for harm to the subject is minimal may be considered under the delegated review process. The FHA REB delegates the Chair/co-Chairs to conduct the delegated review on its behalf. The FHA Chair/co-Chair may for any reason refer a study originally submitted under delegated review to the full board.

g. Emergency Review

(i) The FHA REB reserves the right to convene an 'emergency' meeting of the full REB in order to review studies that arise because of an emergency health care situation and as a result are time-sensitive. The review may be conducted by teleconference with the provision that quorum is met.

h Decision-Making Standards

(i) In considering a study, the FHA REB shall permit researchers to make a face to face presentation to the board but shall not permit the researcher to participate in the deliberations or final decision/vote of the board.

(ii) In considering a study, the FHA REB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available from the REB. These individuals shall not vote with the REB.

(iii) The FHA REB approves studies for a one year term only renewable on an annual basis. The REB also determines which projects require review more often than annually and which projects need verification from sources other than the researcher that no material changes have occurred since previous REB review.

(iv) The FHA REB will not issue a Certificate of Ethical Approval retroactively.

(v) The FHA REB may choose not to approve a research study after due consideration of all documentation and communication received about the study, including that of an external review.

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(vi) Research involving emergency health situations

The FHA REB may decide to approve research that involves health emergencies to be carried out without the free and informed consent of the prospective research subject or of his or her substitute decision maker if ALL of the following conditions are met:

a. A serious threat to the prospective subject requires immediate intervention; and
b. Either no standard efficacious care exists or the research offers a probability of direct benefit to the subject in comparison with standard care; and
c. Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits of the subject; and
d. The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
e. Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
f. No relevant prior directive by the subject is known to exist; and
g. A documented plan is in place to seek free and informed consent promptly for continuation in the study and for subsequent examinations or tests related to the study when a previously incapacitated subject regains capacity, or when an authorized third party is found.

i. REB Declaration Of Conflict Of Interest

(i) An REB member shall disclose any personal interest in the research that is under review.

(ii) The REB member may explain the conflict of interest to the REB and if requested by the REB Chair, may present evidence to the REB and/or provide answers to questions concerning the study. Otherwise the REB member shall absent him/herself from the discussion.

(iii) The REB member shall not be present when the REB is making its final decision.

j. Suspension Or Termination Of REB Approval Of Research

(i). The FHA REB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the FHA Policy *"The Ethical Conduct of Research and Other Studies Involving Human Subjects"* [including Canadian regulations governing clinical trial

research and United States federal regulations governing U.S. government supported research] or that has been associated with unexpected serious harm to subjects or where there are unanticipated problems involving risks to subjects or others. In so doing, the REB shall order the researcher to suspend all subject enrollment and shall determine whether or not all research related procedures should also be stopped.

k. Reporting of Suspension/Termination Of REB Approval

(i) Any suspension or termination of approval shall include a statement of the reasons for the REB's action and be reported promptly to the researcher and the Vice President Academic Development and Clinical Innovation.

4.1.3 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 responsibilities for the ethical conduct of such research and receive appropriate training in the skills necessary for the ethical conduct of such research. This type of training includes promoting an awareness of policies and other relevant standards (e.g., legal, professional and institutional) pertinent to the particular area of research.

b. The Administrative Supervisor must confirm, by signing the application for initial ethical review that the researcher has the qualifications, experience and resources needed to carry out a particular research project as a requirement for the ethics review.

c. In the event that the researcher's immediate supervisor is not available to sign the application, the researcher must make every effort to have the application form signed by the next senior administrator for that person, e.g. Director/Vice President.

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4.1.4 THE FHA RESEARCHER

a. Definition Of Researcher

(i) A researcher who must apply for ethical review and approval by the FHA REB is anyone who carries out research at FHA in the capacity of principal investigator as described under 3.2. **Scope.**

b. Researcher Responsibilities

(i) All researchers involved in carrying out a study are responsible for its ethical conduct. Specifically, the researcher deemed to be the principal investigator for a study is accountable for:

- protecting the rights and welfare of prospective subjects;
- ensuring that pertinent laws, regulations, and FHA policies, procedures and guidelines are observed by participating research staff/collaborators [see b (iv)];
- ensuring that all research involving human subjects receives FHA REB review and approval before commencement of the research [see b (iii) and c];
- complying with all FHA REB decisions, conditions, and requirements;
- obtaining FHA REB review and approval before changes are made to approved research protocols or consent forms [see d];
- assessing the prospective subject's competence to consent;
- obtaining informed consent/assent, as applicable for prospective research, and ensuring that no human subject is involved in the research prior to obtaining their consent/assent;
- ensuring that research studies receive timely annual FHA REB review and approval [see d];
- reporting serious and unexpected adverse events to the FHA REB [see e];
- seeking FHA REB assistance when in doubt about whether proposed research requires FHA REB review;
- disclose any real, potential or perceived conflicts of interest, as well as any institutional conflicts of interest of which they are aware and that may have an impact on their research.

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(ii) The researcher shall seek to obtain the approval of their administrative supervisor [see 3.1.3 b and c] for any research or other study proposed by him/her or proposed by a student working under his/her direction that could be defined as a study involving human subjects prior to submission to the FHA REB.

(iii) The researcher shall submit the proposed study to the FHA REB for ethical review, according to the research ethics board requirements as defined below. The principal investigator for the study shall also submit an up to date curriculum vitae. For details, refer to the "FHA REB Procedure for Submitting Research Studies for Ethical Review" under **Procedure.**

(iv) In so doing, the researcher shall agree to abide by the requirements of the current '*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*' and, where applicable any other national or provincial laws, regulations and standards and/or international regulations and standards, as defined below, in particular for regulated drug, device and natural health product trials, and the FHA Policy *"The Ethical Conduct of Research and Other Studies Involving Human Subjects".*

(v) The researcher shall not begin any activity related to the research study until the FHA REB issues its written approval of the research study.

c. Modifications Required Prior To Obtaining Approval

(i) In the event that the FHA REB requests modifications to the study, the researcher has six months to respond to this request. Failing to respond within this time period shall require a re-submission of the study for ethical review.

d. Amendments Of Previously Approved Research

(i) At any time during the research study if a researcher wishes to amend the research study, an application for amendment shall be submitted to the FHA REB in order to receive a Certificate of Approval for the amendment. No deviations from, or changes of, the research protocol [including consent forms] shall be initiated without prior written REB approval of an appropriate amendment. The researcher shall implement the amendment only upon receipt of the Certificate of Approval for the Amendment.

(ii) An exception is granted if the change in the protocol is necessary to eliminate immediate hazards to the subjects or when the change(s) involve only logistical or administrative aspects of the trial [e.g. change of co-ordinators, telephone numbers].

e. Renewal Of Previously Approved Research

(i) The researcher shall submit an application for renewal of the one year term for ethical approval for any ongoing study BEFORE the approval expiration date. The one year term includes the approval for any amendments during that time period. Ongoing studies are those that meet the following criteria:

- data [including follow up data after subject recruitment is closed] is still being collected directly from subjects, or;
- data is still being collected from secondary sources, for example, medical records and linked datasets, or;
- tissue samples are still being withdrawn from a tissue bank or acquired from another research group for studies which analyze human tissue.

(ii) The researcher shall recruit new subjects/collect data/tissue for the renewal period only upon receipt of the Certificate of Approval for the Renewal.

f. Lapse In Annual Approval For Ongoing Research

(i) If there is any lapse in the annual approval for a previously approved study, the researcher shall be instructed to suspend subject recruitment and, if the research is grant-funded, to notify the funding Agency.

g. Required Reporting For Researchers Conducting Clinical Trials

(i) For clinical trial research and in concurrence with Health Canada requirements, the researcher must report to the FHA REB:

- serious and unexpected adverse event SAEs involving the experimental drug/device/biologic or natural health product being used for the research that are LOCAL within 48 hours and that are INTERNATIONAL within five business days of the researcher's knowledge of the occurrence;
- all deviations from, or changes of, the protocol to eliminate immediate hazards to research subjects;

- changes to the protocol increasing the risk to subjects and/or affecting significantly the conduct of a study;
- updates/changes in the investigator's brochure and/or product monograph;
- data safety monitoring board reports;
- new information that may affect adversely the safety of the subjects or the conduct of the trial;
- any planned full audits (not ongoing monitoring visits) by study sponsor and or regulatory authorities (Health Canada, U.S. Food and Drug Administration, etc.) and report substantive findings within 14 days of the audit completion, and;
- any other deviation as defined below.

h. Required Reporting For Study Closure

(i) The researcher shall provide a notice of study closure to the FHA REB when the study no longer requires renewal as specified above under (e) **Renewal.**

(ii) The notice must state explicitly that there is no further involvement of human subjects with respect to direct contact of subjects, retrieval of secondary sources of data or retrieval of tissue from tissue banks.

i. Researcher Record Keeping

(i) Researchers shall retain copies of certificates of ethical approval and the approved REB documents, and implement a system to comply with approval expiration dates.

(ii) In addition to providing a copy of the signed and dated consent form to each subject, researchers must ensure that a copy of the signed and dated consent form is placed in the subject's hospital record if the subject is a patient.

4.2 The Ethical Review Procedure

4.2.1 GENERAL REQUIREMENTS

a. Required Research Documentation

Researchers shall submit studies to the FHA REB for initial review, amendment of a previously approved study or renewal of a previously approved study. The submission shall include the principal investigator's curriculum vitae/resume, a complete research protocol for ALL studies, the current approved ethics application form, and supporting documentation which may include but is not restricted to consent and assent forms, questionnaires, letters of initial contact and in the case of clinical trials, the Investigator's Brochure. For details, refer to the 'FHA REB Procedure for Submitting Research Studies for Ethical Review' under **Procedure.**

b. Minimal Risk Studies

(i) Submissions that meet the criteria for minimal risk [Refer to Definitions] will normally not be reviewed by the full board, but shall be considered under the delegated review process, as described below.

c. Criteria For Full Board Review Of Amendments And Renewals

(i) Applications for either amendment of a previously approved study OR renewal must be referred to the full board for review if the research is a clinical drug, device or natural health product trial regulated by Health Canada and the amendment involves any of the following changes:

- Addition of genetic testing, new genetic tests or tissue banking where genetic testing may or will be performed;
- Addition of an open label extension phase following a randomized trial;
- Emergency amendments that arise because of subject safety concerns and that are submitted after implementation as a result, and;
- Significant changes to a protocol that may affect subject safety and may include a (but are not limited to):
    - change in drug dosing/duration of exposure,
    - decrease in monitoring,

- change in recruitment technique that may affect confidentiality or the perception of coercion,
- change in experimental procedure or study population.

(ii) Applications for either amendment of a previously approved study or renewal may also be referred to the full board for review if any of the following conditions apply.

- the research is funded by the United States Department of Health and Human Services (DHHS) (e.g. NIH and its related institutes including NCI, U.S. Centre for Disease Control) under 45 CFR 46.109 (e) and 46 CFR 110 (Code of Federal Regulations) as defined below under international standards.
- the research is funded by other American federal agencies (e.g. United States Department of Defence) under 21 CFR 56.110, as defined below under international standards.

4.2.2 FULL BOARD REVIEW

a. The FHA REB meets regularly on a face to face basis to review proposed research not delegated to the Chair/co-Chair for delegated review [see 4.3.2].

b. The FHA REB shall meet on the second Tuesday of the month or as otherwise advertised on the FHA intranet ethics site. The deadline for submissions to the Board is two weeks prior to the meeting date or as otherwise advertised.

c. (i) The FHA REB shall read and evaluate each complete research study submission and decide for the relevant proposed or ongoing research whether to:

- approve it;
- require modifications to it and/or a response to questions;
- defer the study [see (iii) below];
- not approve it; or
- terminate it

See 'Definitions' for an explanation of each term.

(ii) When the FHA REB decides to request modifications to the research study or to reject it, the REB shall provide the researcher with its written reasons for doing so and shall give the

researcher an opportunity to respond within a six month period at which time the REB shall request a re-submission of the entire study.

(iii) The FHA REB may delegate the review of the researcher's response to this request to the Chair/co-Chair.

(iv) The FHA REB may decide that the research must be "Deferred" because of major and substantive concerns about the study. The REB shall notify the researcher in writing of these concerns and request that the researcher's response to these concerns be submitted for full board review. The REB shall give the researcher an opportunity to respond within a six month period at which time the REB shall request a re-submission of the entire study.

d. FHA REB decisions shall usually be made by consensus. Where consensus is not achieved the decision shall be made by majority vote which shall constitute seventy per cent (70%) of the members in attendance at the meeting. Only those members who participate in the review and discussion shall make a decision by either consensus or vote.

e. The FHA REB may also decide the frequency of continuing review if other than an annual review is required for a particular research study.

f. Research that has been approved shall receive a Certificate of Approval for the submission. The Certificate reflects whether the approval is for initial review, amendment of a previously approved study or renewal of a previously approved study.

4.2.3 DELEGATED REVIEW

a. New proposed research that meets the definition of minimal risk [See Definitions] and submissions for which the potential for harm to the subject is minimal may be considered under the delegated review process.

b. Delegated review may be possible for the following types of submissions:

- a new application with minimal risk to subjects with the exception of any studies which: 1) have industry funding; 2) involve subjects who are incompetent and therefore are deemed by the researcher to be incapable of providing full consent;
- research involving patient record review;
- review of minor amendments to a research study that has already been approved;
- renewal of time-limited approval where there is little or no change in ongoing research;
- affirmation that modifications required by the FHA REB have been met.

Refer to 'Definitions' for other examples of research in this category.

c. The Chair/co-Chair may at any time and for any reason refer a study originally submitted for delegated review to the full board for review.

d. The Chair/co-Chair reviews the research study for its ethical, scholarly and scientific acceptability.

e. The Chair/co-Chair may request either that the researcher modify/respond to questions about the study which they will review and approve upon submission of a satisfactory response OR approve the study.

f. If modifications are requested, the Chair/co-Chair shall provide the researcher with the written reasons for doing so and give the researcher an opportunity to respond within six months before making a final decision.

g. A Certificate of Approval shall be issued when the study is approved by the Chair/co-Chair. The Certificate reflects whether the approval is for initial review of a minimal risk study, amendment of a previously approved study or renewal of a previously approved study.

h. The Chair/co-Chairs shall refer any research to the full board if there is a concern that it should not be approved.

i. The delegated review decisions of the Chair/Co-Chairs for new minimal risk studies are reported to and ratified by the full FHA REB prior to the release of the Certificate of Approval to the researcher.

4.2.4 REVIEW OF SERIOUS AND UNEXPECTED ADVERSE EVENTS, PROTOCOL DEVIATIONS/VIOLATIONS AND OTHER SUBJECT SAFETY ISSUES

a. The FHA Chair/co-Chair shall review serious adverse events (SAEs), protocol violations and any other matters brought forward by FHA researchers that affect the safety of research subjects. The review of local serious adverse events shall be reported to the FHA REB.

4.3 Research Subject Concerns

a. The Chair/co-Chair shall respond to any concerns brought forward by research subjects regarding the conduct of a study in which they are participating. The Chair/co-Chair shall direct these concerns as necessary to the Vice-President Medicine.

4.4 Term Of Ethics Approval

a. The Certificate of Initial Approval is valid for one year from the date of the approval by the FHA REB or the Chair/co-Chair and expires at the end of the one year period.

b. The Certificate of Renewal is valid for a one year period only and expires at the end of the one year period.

c. The Certificate of Approval for an Amendment granted within the one year term of the initial approval or subsequent approval is valid only for the one year period of the initial approval or subsequent one year renewal.

4.5 Requests For Modifications Of Proposed Research

a. Any FHA REB request for any modifications to studies should be responded to within six months from the date of issue of the request. Failing to do so will require a re-submission of the study for ethical review.

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4.6 Appeal Procedures

a. The decision of the FHA REB to not approve an individual study cannot be overridden except by formal appeal of the researcher to the VP. The appeal is a last resort after all attempts to resolve differences between the researcher and the FHA REB have been made.

b. The VP shall permit review at his/her discretion, of the FHA REB decision to not approve a research study.

c. The VP shall appoint an independent research ethics board to undertake the appeal.

d. The research ethics board shall not be affiliated with FHA, shall be constituted to act as an Appeal Board and shall meet the REB membership requirements of the Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans and the regulatory requirements for REB membership relating to the review of regulated trials.

e. No person shall serve as a member of the Appeal Board with respect to a review of a FHA REB decision if that person was a member of the FHA REB that made or reconsidered the decision or if that member has any conflict of interest with respect to the study at issue.

f. Appeal members must declare any conflict of interest concerning the review of the study under review by completing a conflict of interest declaration form prior to the review of any study under appeal.

g. The Appeal Board must take into consideration how the FHA REB applied the requirements of the *'Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans'* and other relevant [including regulatory] requirements.

4.7 Co-operative Review

a. In complying with these regulations, the FHA REB may choose to consult with another qualified REB if the research concerned is multi-jurisdictional.

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4.8 Record Keeping

a. The following records shall be maintained for a period of 25 years and are available to the FHA, FHA REB for research monitoring purposes, FHA researchers, funding agencies, Health Canada and other applicable authorities involved in the oversight of the research being conducted:

- applications for ethical review, including research protocols and all other submitted documents for individual studies and any related correspondence;
- the minutes of all FHA REB meetings which document the REB's decisions and any dissents, and the reasons for them;
- the written FHA REB standard operating procedures, policies and guidances, and;
- the FHA REB membership lists including their occupation/affiliation.

REFERENCES

1. The Tri-council Policy Statement on Ethical conduct for Research Involving Humans
Refer to: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

2. The Declaration of Helsinki
Refer to: http://www.wma.net/en/30publications/10policies/b3/17c.pdf

3. The Belmont Report
Refer to: http://ohsr.od.nih.gov/guidelines/belmont.html

4. FHA REB Standard Operating Procedures

5. FHA REB Guidance Notes and Policies

6. FHA REB Consent/Assent Form Templates

7. FHA CORPORATE RESEARCH-RELATED POLICIES:

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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