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LIST OF FH REB APPROVED POLICIES

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Research Ethics Board

Requirement for Research Protocol	**Policy No. 1** Approved 12 April 2005 Revised 18 November 2008

The FH REB requires that a research protocol/research plan be submitted for all types of studies, including pilot studies and retrospective chart reviews. The research proposal submitted to granting agencies may be used to meet this requirement; in this case, ensure that the appropriate section of the grant application is referenced. For all other studies, including those that are submitted for expedited review, investigators must submit a protocol that includes the following components:

1. Table of Contents
2. Study Protocol Summary or Abstract
3. Background Information
4. Purpose of Study
5. Hypothesis (if applicable)
6. Justification for Study
7. Objectives of study
8. Research Method (including data collection methods)
9. Sample Size
10. Statistical Analysis Plan
11. Justification if the study has a placebo-control (if applicable)
12. (refer to http://www.cihr-irsc.gc.ca/e/25139.html for appropriate use of placebos in clinical trials in Canada)
13. Subject Inclusion Criteria,
14. Subject Exclusion Criteria
15. Research Procedures
16. Potential Benefits
17. Subject Safety Provisions, i.e. un-blinding, data monitoring, and stopping rules

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Research Ethics Board

Telephone Contact For Obtaining Consent in Emergency Situations	**Policy No. 2** Approved 12 April 2005 Revised 02 July 2010

The FH REB does not allow initial contact by telephone, except under unusual circumstances where timely consent is required, but no Substitute Decision Maker (SDM) can be present in that time-frame.

1. This consenting procedure may be used only when the principal investigator or designate cannot speak to the SDM in person. Telephone contact may be allowed if the SDM has not arrived with the potential study subject and is not expected at the hospital within the time limit of the study initiation.
2. The principal investigator or designate will present the information in the consent form over the phone and provide any clarification required.
3. Once the SDM of the patient has been fully informed of the patient's medical condition by the attending physician, the study will be discussed by one of the Investigators. The Principal Investigator or Co-investigator will read the entire consent form over the telephone and provide any clarification requested by the SDM.
4. When all questions have been answered to the satisfaction of the SDM, the call will be terminated to provide an opportunity for the SDM to consider the study. Once a minimum of 30 minutes have passed, the Investigator (and witness) will again contact the individual for their decision (This is done so the family does not have to bear the costs of long distance charges).
5. A witness to the telephone consent, in addition to the Investigator reading the consent form, will be on the telephone line to hear the reading of the consent form and the verbal granting or refusal of consent by the SDM.
6. The identity of the witness will be disclosed to the SDM prior to the reading of the consent form.
7. The date and time that the telephone consent is obtained, the names of the SDM, the Investigator (reader), and the witness will be entered into the original consent form.
8. Whenever possible the consent form will be emailed and/or faxed to the SDM prior to the reading of the form, enabling them to follow along as it is read to them. If the SDM agrees to participate they will be instructed to sign the form and fax it back to the principal investigator. If the SDM does not have access to a fax, the SDM may send an email acknowledging that he/she has received and read the consent form and is agreeing to allow the subject to participate in the study. Following the email, the signed consent form should be sent to the principal investigator by mail.
9. Written evidence of consent will subsequently be obtained in a timely manner after obtaining verbal consent.

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Research Ethics Board

Remuneration in Recruitment Materials	**Policy No. 3** Approved 12 April 2005 Revised 18 November 2008

Recruitment materials that are used for the purpose of recruiting subjects, such as letters, advertisements, flyers, radio or television scripts, or internet messages, must not include any information about the value of the remuneration for participation.

Minimal risk studies – The FHREB believes that it is acceptable to advertise the details of reasonable remuneration for participation in minimal risk studies that involve interviews, focus groups or the completion of questionnaires or other types of non-invasive data collection given the understanding that there is no expected benefit from this type of research. Refer to **GN 15** for guidance on the acceptable value of the remuneration.

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Provision of Pre- and Post-Test Counseling	**Policy No. 4** Approved 12 April 2005

If in the course of research, there are tests that might have results that impact seriously on the research subject's health or have other serious implications (e.g. HIV or some genetic tests), appropriate pre- and post-test counseling services shall be made available to that person, and, when appropriate, to his or her family.

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Research Ethics Board

Information Required For Subjects Identified As High Risk As A Result Of Genetic Status	**Policy No. 5** Approved 12 April 2005

The consent form must include a statement that informs subjects that any knowledge gained from the research study, that identifies the subjects as belonging to a high-risk group, may reduce the ability of the subject to obtain health and/or life insurance.

The only reason not to tell the subject about this potential risk is if the risk of developing the disease is high based on family history and is not heightened by knowing their genetic status.

Research Ethics Board

Disclosure of Reasons For Not Receiving Study Treatment After Subject Research Participation is Completed [1]	**Policy No. 6** Approved 12 April 2005

The following statement shall be required in the Consent Form for any trial involving any drug or other experimental therapy, which is of a chronic nature:

"AFTER THE STUDY IS FINISHED:
You may not be able to receive the study treatment after your participation in the study is completed. There are several possible reasons for this, some of which include: The treatment may not turn out to be effective or safe. The treatment may not be approved for use in Canada. Your caregivers may not feel it is the best option for you. You may decide it is too expensive and insurance coverage may not be available."

[1] These policies have been adopted by the FH REB with the permission of the University British Columbia Clinical Research Ethics Board

Research Ethics Board

Identifiers Not Permitted On Study Related Documents	**Policy No. 7** Approved 12 April 2005 Revised 18 November 2008

The FHREB expects that research-related documents (except the master randomization schedule, consent forms, or screening logs) do not include information that would allow the subject to be identified.

Information is considered de-identified if the following conditions are met:

1. the unique study code is not derived from or related to the information about the individual;
2. the unique study code could not be translated to identify the individual, and;
3. the investigator or their institution could not use OR disclose the unique study code for other purposes OR disclose the mechanism for re-identification.

To this end, spaces/fields for subject name, the first or last three letters of a subject's name, actual initials, reversed initials, birth date, hospital medical record number, provincial personal health number, social insurance number, address or phone number are not permitted on study-related documents. Because many other people know/could access these identifiers, they provide less protection of privacy than the use of a unique study code.

Date of Birth: The FHREB will accept the use of month and year only, as an identifier.

It is not necessary to use a personal identifier (for example, birth date) as a secondary identifier in order to confirm the identity of the subjects. This can be accomplished by using any two unique study codes.

Subject Enrollment Logs, documents or databases, which correlate subject names with study code numbers, must be kept on the locked premises of the Principal Investigator or in an appropriately secured electronic form.

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Research Ethics Board

Translated Consent Forms	**Policy No. 8** Approved 12 April 2005

Translated copies of the consent form(s) will be required for acknowledgement after the FHREB has approved the English version of the consent form. A copy of the translator's signed and appropriate confirmation of the accuracy of the translation must accompany this; or,

Consent forms originally written in other languages must be translated into English and the back translation submitted for ethical review. (Updated 24 September 2004)

If a translator enrolling a subject is using an English consent form, the consent form must include the signature and printed name of the translator and the name of the language it was translated into.

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Research Ethics Board

Criterion for Permitting Mandatory Tissue Banking	**Policy No. 9** Approved 12 April 2005 Revised 18 November 2008

Tissue is defined as including blood. Mandatory tissue banking is only permitted if the tissue is being banked for purposes **directly related** to the study at hand (i.e. the tissue banking must be integral to the study, such that there would be no study if the subject did not contribute the tissue).

It is unethical to *require* that subjects agree to allow their tissue to be banked for future use or experimentation that is unspecified or unrelated to the study at hand as a condition for entry into a therapeutic trial, as this could be perceived as a coercive method of obtaining tissue/blood samples through offering a perceived therapeutic opportunity.

Research Ethics Board

Voluntary Donation Of Tissue For Unspecified Uses	**Policy No. 10** Approved 12 April 2005

Subjects *may* donate their tissue for future, unspecified uses provided:

1. this condition is made explicit in the main consent form for the study;
2. that such donation is optional, and;
3. that the Investigator discloses whether or not they plan to seek the subjects' consent for future projects involving their tissue.

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Research Ethics Board

Confidentiality	**Policy No. 11** Approved 12 April 2005 Revised 18 November 2008 Revised 20 June 2012

The following requirements must be in place in order to protect subject confidentiality, but at the same time to allow monitoring of any study to occur. The consent form must include the following, as applicable, along with an explanation about the type of information that will be collected about the research subject.

a. De-identification:

An explanation of how the subject's information has been de-identified. If de-identified, the consent form must explain what type of unique code is used and an explanation that the list that links/matches the subject's name to the unique code and therefore to the subject's research-related information is kept by the principal investigator and/or designate ONLY, under secure conditions, so that it cannot be accessed by unauthorized personnel. See Standard Confidentiality Wording below.

OR

b. Use of Non-standard Identifiers:

When sponsors require that identifiers other than a unique study code be used on research records, justification for such use including their intended use must be provided to the FHREB. Include details of how the subjects' confidentiality will be protected despite the use of the non-standard identifiers. The following standard wording is required and should be added to the Standard Confidentiality Wording as appropriate:

"It is unusual to include [name the non-standard identifier(s), e.g. date of birth/reversed initials] on research records and material forwarded to others. Most studies submit information identified by code numbers or letters only."

OR

c. Anonymization:

If the information is anonymized such that it does not include any identifiers, the consent form must explain that the research information will not identify the subject in any way. The following standard wording is required:

"Your research-related information will not identify you in any way because all identifying information has been removed such that the information is now anonymous and there is no possibility of linking your identity to your information."

d. Availability of Records For Monitoring:

Records must be made available to a scrutineer from an industry sponsor (in the case of sponsored clinical trials), Health Canada (in the case of regulated clinical trials), the U.S. Food and Drug Administration (in the case of American regulated clinical trials), and the Fraser Health Research Ethics Board, provided that it is done in the presence of the Principal Investigator or his or her designate and that the records are not copied or the names recorded. The consent form must explain that identifiable information from source research-related records may be inspected for regulatory, legal and ethical review requirements. See standard wording below:

e. Standard Wording for Confidentiality Disclosures:

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of *[**Insert here, if relevant to study,** the name of the sponsoring company or cooperative group conducting the study],* Health Canada, *[**Insert here, if relevant to study,** the U.S. Food and Drug Administration],* and *[**Insert name of your REB]*** for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law. [If this is a US FDA regulated study, insert the sample paragraph noted below that describes the right of the US FDA to remove identifying information.]

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

For US FDA-regulated studies only, include the following wording in separate paragraphs:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. [This is mandatory US FDA wording and cannot be amended.]

Because this is a study that also falls under U.S. regulation, in some circumstances the U.S. Food and Drug Administration (US FDA) may seek to copy records that contain your personal information. If this occurs, you will be informed before the records are copied, but your consent may not be sought. You should be aware that privacy protections on personal information may differ in other countries.

NOTE: If there is planned disclosure of personal identifiers (e.g. names, date of birth, or initials) outside the local study site, or if such personal identifiers are used on study documents or any research-related information or are part of the unique identifier, this must be justified to the REB and, if permitted, the foregoing standard wording must be amended as necessary. As well, placement of any research data or results in the subject's health records must be disclosed to subjects and justified to the REB.

Sample Wording (if applicable):

Your birth date will also be provided if requested by the sponsor or responsible regulatory agency.

f. Research-related Records Leaving the Research Site:

For studies, which require that information be copied, or leave the FH site, include an explanation in the consent form that states specifically what information is leaving the site and where it is going. Note that this explanation should be consistent with the explanation about the use of identifiers, if any.

g. Research-related Records Sent Outside of Canada

<u>If data is being transferred out of Canada</u>

The following information must be included in the consent form:

1) What subject information will be sent outside of Canada.
2) A description of the coding of the data if different from above.
3) To whom the information will be sent (i.e. individuals, organizations, regulatory agencies)
4) Where the information will be sent (i.e. USA, UK, Australia)

If data and/or samples will be sent outside of Canada, clarify if it is data and/or samples and include the following wording:

Any study related data [or samples], sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries *[for example, the Patriot Act in the United States]* dealing with protection of information may not be as strict as in Canada. However, all study related data [and samples], that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information *[and samples*], to organizations located outside of Canada. *[Include list of organizations.]*

h. Archiving Research Records:

When investigators must archive research records off-site, they are responsible for the security and confidentiality of the data. The FHREB still considers the data to be "in the Investigators' offices" for the purposes of the wording used in the confidentiality statement.

i. Mandatory Disclosure of Subject's Identity: Reportable Communicable Diseases/Suspected Child Abuse:

In rare instances it will not be possible to ensure confidentiality because of mandatory reporting laws (e.g., suspected child abuse, reportable communicable diseases, and knowledge of harm to others). When this is the case, the prospective research subject should be made aware of this limitation in the consent form.

The BC Health Act Communicable Disease Regulation Schedules A & B list reportable diseases. Sections 2(1), 2(2) and 2(3) require physicians/researchers to report communicable diseases (e.g. HiV, HCV) to the Medical Health Officer. Reporting includes the name, age, sex and address of the infected person.

The only exception to mandatory reporting is for persons who voluntarily submit to testing for HiV; for which a non-nominal report is permitted (i.e. the report must omit the name and address of the person if that person so chooses).

Anonymous surveys that are unlinked do not fall within the reporting requirements of the Act as the physician/researcher would not know that any particular individual was infected.

Standard wording is required for any research studies in which blood tests may reveal the presence of a communicable disease that is reportable by law. Refer to the BC Health Act Communicable Disease Regulation Schedules A & B for the list of reportable diseases at http://www.qp.gov.bc.ca/statreg/reg/H/Health/4_83.htm.

In addition, standard wording is also required for notification of suspected child abuse for studies involving children.

Required Wording: Use the standard wording for either blood tests for communicable diseases [see a below] OR studies involving children or harms to others [see b below] that is applicable to the study.

In most cases, your personal information or information that could identify you will not be revealed without your express consent. However, if as a result of your participation in this study, facts become known to the researchers which must be reported by law to public health authorities or legal authorities, then your personal information will be provided to the appropriate agency or authority.

j. Potential for Breach of Confidentiality:

The following statement concerning the possibility of a breach of confidentiality is permissible in the consent form: No information or records that disclose your identity will be published

without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law. This wording means that there is an absolute obligation to keep confidentiality until such time as there is an exception arising out of a legal requirement to disclose a subject's identity. Other wording, i.e. "to the extent permitted by law" is generally not permissible as this implies that there is not an absolute obligation to keep confidentiality.

k. Photography, Video / Audio Taping:

If there are any plans to use photography (including digital photographs), video or audio taping in the research, who will have access to the recordings and the methods used to protect the subject's identity must be described in the consent form. The eventual fate of the records must also be disclosed (i.e. where and for how long they will be stored and whether they will be destroyed, any plans for secondary uses of the recordings). If there are plans to use these materials for any other purpose than the research project (e.g. for teaching purposes) and subjects could be identified, separate consent is required.

l. Disclosure of Inclusion of Signed Consent Form in Subject's Health Record:

If the subject is a patient in an institution (e.g. hospital) when the research is conducted, inclusion of the signed Consent Form in their permanent health record in Fraser Health is required and if so, this must be disclosed in the Consent Form. The requirement for inclusion of the Consent Form in the health record may vary between other non-FH institutions, and investigators should seek clarification from the institutions involved.

m. Disclosure of Test Results in Subject's Health Record:

If it is the intention or a likely consequence of the research that test results which might affect treatment decisions or have important implications (e.g. HIV tests, genetic tests) will become part of the subject's health record, this must be disclosed in the Consent Form.

Research Ethics Board

Compensation for Injury	**Policy No. 12** Approved 12 April 2005 Revised 12 February 2008 Revised 18 November 2008

The following wording will be required to appear in the subject consent form under the Compensation for Injury section:

"By signing this form, you do not give up any of your legal rights and you do not release the study doctor or other participating institutions from their legal and professional duties. *There will be no costs to you for participation in this study*[1]. You will not be charged for any research procedures. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan and*/or by the study sponsor.* [Name the Sponsor]*[2]*.*

[1] *include if statement is true for this study, i.e. all parking, mileage expenses are being reimbursed to the study subject.*
[2] *not necessary for non-regulated studies or unfunded studies"*

*Definition of "Sponsor" Refer to ICH Good Clinical Practice Guidelines (ICH GCPs) (1997) [Updated 2008 August 08] http://www.ich.org/MediaServer.jser?@_ID=482&@_MODE=GLB

The following statements are not permitted because they may be seen to limit the circumstances under which compensation for injury is available:

"Although no funds have been set aside to compensate me in the event of illness or injury related to the study treatment or procedures" OR "While participating…through to "guarantee full coverage", OR There will be no financial compensation…" for damages (e.g. lost time from work, disability or discomfort)" OR "compensation for…. is not routinely available.".

Research Ethics Board

FH REB Approval Statements in Consent Form	Policy No. 13 Approved 12 April 2005

The FH REB accepts (but does not require) references in consent forms to the project having been reviewed and/or approved by the Research Ethics Board. When mentioning the Research Ethics Board, the FH REB accepts (but does not require) an explanation of the Board's role in terms similar to the following: "This Board aims to help protect the rights of research subjects."

Note that no mention of risks will be accepted in describing the role of the REB so as to avoid the misinterpretation that the REB's oversight makes it safe for subjects to participate in the research.

Research Ethics Board

Use of "Negative Consent" Check Boxes in Consent and Assent Forms	**Policy No. 14** Approved 12 April 2005

The use of "Yes/No" check boxes for consent is not allowed. Lack of signature on a consent form is taken as evidence of dissent, and no subject shall be required to declare in writing in any way that they do not consent to participate in a research project.

Exception to #1:
1a. Where a single consent form contains multiple optional sub-components, (e.g. tissue banking for genetic research) where subjects can choose which ones they wish to participate in, the optional SUB-COMPONENTS (but not the main question of consent to participate in the main project) may employ "Yes/No" indicators to signify willingness to participate.

Lack of indication of "Yes" (or equivalent) shall be taken as evidence of DISSENT and no requirement to check "No" (or equivalent) is allowed.

The FH REB may require that *separate* consent forms fully describing a sub-component(s) of a project be required instead of allowing the procedure described in 1(a) where necessary.

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Co-Investigators Listed on Consent Forms	Policy No. 15 Approved 12 April 2005 Revised 11 March 2008

1. The FHREB prefers that all co-Investigators, their institutional affiliation (i.e. use the local site in a multi-site trial) and appropriate titles be listed after the Principal Investigator on both page 1 and the Subject Consent to Participate page of the consent form. (The purpose of including all investigators names is to enable release of health records to any investigator in the study team for that subject.)

2. Where it is not practical to do so, the Board accepts that only the Principal Investigator (including their telephone number) be listed on the consent form.

3. Where a subject's "study doctor" is other than the Principal Investigator, a place must be provided in the consent form for this person to be named, and their telephone number provided.

4. Choice of listing of the Principal Investigator and co-investigators does not affect the requirement for an emergency 24 hour contact number for subjects enrolled in the research.

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Conflict of Interest	**Policy No. 16** Approved 12 April 2005

At a minimum, potential conflicts must be disclosed to the Board and to potential subjects. The Board may require further action of the researcher to minimize or abandon a conflict, require formal oversight procedures for the research (including audits, independent data safety monitoring processes, regular reports to the FH REB), or may disallow the research altogether. The Board may also inform the investigators' Department Head or Dean of Faculty about the conflict of interest.

Research Ethics Board

Obtaining Assent From Subjects Who Are Legally Incompetent	Policy No. 17 Approved 12 April 2005 Revised 18 November 2008

The FHREB requires researchers to ascertain the willingness of individuals to participate in the research if they are legally incompetent but can nevertheless understand the nature and consequences of the research. These individuals will normally be required to assent by verbal or physical means or to sign an assent form before they can participate in research. These requirements may apply even though free and informed consent has been obtained, or is available, from an authorized third party.

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Disclosure of Research-Related Harms for Clinical Trials	**Policy No. 18** Approved 12 April 2005 Revised 18 November 2008

The FHREB requires that research-related harms must be identified and quantified in the subject consent form. Any risks related to standard care must be identified and explained to the subject by their study doctor. An explanation of this must be included in the consent form when standard care is involved.

EXCEPTION: The FHREB may require the risks of standard care to be identified and quantified in comparison with those of experimental procedure if that standard of care required in the protocol is not the standard of care currently used in the Fraser Health Authority. This decision will be made on a case by case basis and will be at the discretion of the FHREB. The principal investigator will be informed of any such decision by the FHREB.