

<b><u>POLICY TITLE</u></b>		
<b>INTELLECTUAL PROPERTY</b>		
<b><u>AUTHORIZATION</u></b> Vice President, Academic Research and Clinical System Redesign	<b><u>DATE APPROVED</u></b> February 2008	<b><u>DATE REVISED</u></b>

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## 1. PURPOSE

The purpose of this policy is:

- 1) to encourage and support innovation and research in Fraser Health [FH<sup>1</sup>]. This policy describes the rights and responsibilities, regarding ownership, use and control of intellectual property [IP], of FH and of the FH employees and privileged physicians who develop or participate in the development of IP, which includes for the purposes of this policy the definition below, but also research data and research tools, and all proprietary information and know-how related to any of the items covered under the definition, and;
- 2) to describe the transfer of innovative knowledge arising from research- or work-related activities into the public domain.

### 1.1 Definition of Terms

#### a. Intellectual Property

Intellectual property is defined simply as any form of knowledge or expression created with one's intellect. It includes such things as [inventions](#), computer software, trademarks, literary, artistic, musical or visual works, '[Know-how](#)', as well as trade secrets, plant breeders' rights, integrated circuit designs and personality rights, such as the right to an image.<sup>2</sup>

These rights are "property" in the sense that they are based on the legal right to exclude others from using the property and in that ownership of the rights can be transferred. The rights are "intellectual" in the sense that they protect intangible subjects, usually arising out of some form of human creativity.

Inventions may be protected by [Patent](#), as regulated under the most current version of Canada's *Patent Act*<sup>3</sup>, and by Registered Industrial Design. An invention is deemed to be 'made' when it is first conceived or first actually reduced to practice.

Patents protect [inventions](#), such as machines, devices, methods, industrial designs and compositions of matter. Invention as regulated under the *Patent Act* means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. For the purposes of this policy, inventions are also taken to include computer software, research data and research tools, and all proprietary information, know how and trademarks related to any of these items. The invention may or may not be patentable.

<sup>1</sup> FH is used to denote Fraser Health Authority throughout the rest of this document.

<sup>2</sup> Intellectual Property Institute of Canada (IPIC), Downloaded from <http://www.ipic.ca/english/general/> and, Canadian University Intellectual Property Group. A Guide to Protecting Intellectual Property. Downloaded from <http://www.research.utoronto.ca/ipc/cuipg.html>

<sup>3</sup> Canada. Department of Justice. *Patent Act*, R.S.C. 1958, c. P-4, s. 2

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Copyright is the exclusive right of the copyright owner to (a) produce and reproduce an original literary, artistic, musical or dramatic work (or any substantial part thereof) in any material form; and (b) to permit another individual or organization to do so. For the purposes of this policy copyright is described by the most current version of Canada's *Copyright Act*.<sup>4</sup>

Trademark rights protect words, designs, numbers, two-dimensional or three-dimensional forms, sounds or colors (or a combination of two or more of these elements) used to distinguish the products or services of one trader from those of others in the marketplace.

#### b. IP Management

IP management is defined as the identification/assessment, protection, promotion, and/or commercialization of IP.<sup>5</sup>

For the purposes of this policy, other definitions and terms are found in Section 5 Definitions.

## 2. PHILOSOPHY

FH has a commitment to foster new ideas and innovation, to be open to new evidence-based research findings and to be focused on outcomes. To these ends, FH supports the development of intellectual property that may arise out of either the research or work-related activities of FH employees and privileged physicians. In so doing, FH shall endeavour to ensure that any benefits arising from the development of IP become available to the general public if practical.

## 3. POLICY

### 3.1 Scope

a. This policy applies to:

- i. FH employees and privileged physicians who have developed IP as defined by this policy in which FH resources [i.e. working in facilities owned and operated by FH; using equipment, supplies, personnel and confidential information] or funds administered by FH are used and which arises from either research or work-related activities carried out on behalf of FH;
- ii. research funded wholly or in part by a commercial sponsor as modified by the provisions of the agreement covering such work between the researcher, FH and the sponsor;
- iii. research funded by a not for profit granting or government agency;

<sup>4</sup> Canada. Department of Justice. *Copyright Act* R.S., 1985, c. C-42. Available at <http://www.cb-cda.gc.ca/info/act-e.html>

<sup>5</sup> Statistics Canada, Science, Innovation and Electronic Information Division; Survey of Intellectual Property Commercialization in the Higher Education Sector, 2005

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- iv. research conducted by researchers affiliated with FH as modified by the provisions of the agreement covering such work between the [affiliated researcher](#) , the affiliated researcher's institution and FH;
  - v. education and information materials, published or not published, developed as a result of activities conducted in FH facilities or using funds administered by FH, and;
  - vi. other corporations or individuals external to FH whom FH may hire to carry out work on a contractual basis, as for example, an independent contractor or a contracted services employee.
- b. Individuals or corporations external to FH who are hired as contractors, a contractor's employees and subcontractors shall be required to waive any rights over any IP or copyright that could arise from their work carried out on behalf of FH.

### 3.2 IP Arising Out of Research or Work-related Duties

The following section concerns IP that has commercialization potential. However where the product developed out of research or work-related duties could be readily used by another British Columbia public body, commercialization may not be possible and FH may choose only to recover its costs.

#### 3.2.1 Disclosure and Confidentiality

- a. A confidential [disclosure](#) shall be made to FH of any IP, as defined by this policy, arising out of research or work-related duties, that has the capability of being patented or licensed for the purposes of commercialization. See [Procedures](#).
- b. Information about IP disclosures shall be kept confidential [i.e. the [Creator\(s\)](#) and others having knowledge of the IP shall not make known information about the disclosure to parties that are not bound by appropriate confidentiality agreements with FH] until FH advises that such information can be released in order not to destroy the possibility of obtaining valid patent rights.
- c. An invention may be disclosed to third parties prior to filing a patent application, provided the disclosure is covered by a [Confidentiality Agreement](#) between FH, the Creator and the third party to whom the invention is disclosed. Such agreements provide evidence that the receiving party understands the confidential nature of the information and expresses in written form its obligation to keep the information in confidence.

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### 3.2.2 Assignment of IP Rights

- a. The [assignment](#) of rights to the IP shall be to FH unless there has been a prior arrangement to the contrary which is governed by special agreements concerning ownership between commercial sponsors and FH, and/or between the institution of an affiliated researcher(s) and FH, and/or between FH and a government agency.
- b. In cases where a Creator subject to the FH Intellectual Property Policy is also subject to the policy of another organization (e.g. hospital, health authority, or other external institutions), the determination of rights to a FH invention and the allocation of net revenue, equity and net proceeds arising out of the commercialization of the FH invention shall be subject to the terms and conditions of agreements between FH and the external institution in force at the time of disclosure of the FH invention, or in the absence of such an agreement to negotiation between the institutions involved.
- c. The assignment shall not imply that protecting or commercializing the IP by FH will necessarily occur. FH may choose to protect, develop or commercialize the IP in the manner that FH deems appropriate.
- d. Where it is anticipated that inventions or discoveries may ensue from a particular funded research enterprise, it may be necessary to undertake special agreements concerning patent or licensing rights before research funds are accepted for administration by FH.
- e. Should FH decide not to protect, develop or commercialize the IP, FH may choose to reassign its rights to the Creator, following which the Creator has the right to decide whether he/she would like to commercialize their invention.
- f. Reassignment shall be done in a timely manner.
- g. Failure of FH to secure a signed patent agreement in no way affects the responsibilities or obligations of any party under this Policy.

### 3.2.3 IP Development and Commercialization by FH

- a. Creators shall co-operate in the development and marketing of the invention, assist in preparing patent applications and ensure that written descriptions and patent filings are complete and accurate, and sign all necessary legal instruments from time to time relating to licensing or the filing and maintenance of patents and the development of the invention.
- b. Creators shall not use the name of FH in any way including, without limitation, in connection with the development or commercialization of an invention without the prior written consent of the Vice President Academic, Research and Clinical System Redesign.

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- c. Creators shall ensure that persons who work under their direction and who do not contribute any original thought to the claimed invention are not named as an inventor. Professional collaborators may or may not contribute to the inventive concept being claimed. The type of relationship shall be delineated clearly in writing before research or development work is undertaken relative to the project or activity.
- d. Should FH decide to retain its right and to commercialize the IP, any such commercialization shall be undertaken at FH's expense
- e. FH may choose to undertake the commercialization process using the services of an established technology transfer provider.

### 3.2.4 Proceeds of Development and/or Commercialization of IP

- a. Under the terms of this policy, Creators [including employees and privileged physicians] may share in the proceeds of the development and/or commercialization of their IP, if this is undertaken by FH. A sharing of any income arising from the development and/or commercialization of the IP between the Creator(s) and FH would be arrived at by bi-lateral agreement. Where several individuals collaborate on an invention, any share of the net profit shall be divided among them in such manner as they decide. FH shall be given written notice of the decision at the outset of the disclosure which shall include the names of all interested parties.

The share of any net profit to be allocated to the Creator(s) may be varied by FH from time to time by written agreement with the Creator.

- b. [Remuneration](#) (i.e. income derived from the sale or other disposal by FH of inventions, including that derived under the terms of agreements with patenting corporations) received by FH from each invention shall be applied in accordance with the following priorities:
  - i. Repayment of [direct costs](#) incurred by FH;
  - ii. Payment of payments (if any) due to not-for-profit granting agencies or third party sponsors;
  - iii. The balance, being the net profit, shall be allocated to the Creators who have collaborated on the invention and to FH.

#### 3.2.4.1 Commercialization by Creator

- a. Should FH decide to retain its interest in the IP, but not to participate in its commercialization, the IP shall be reassigned to the Creator. The reassignment of the IP to the Creator shall include a provision that FH shall have the right to receive [remuneration](#), including a share of [gross revenue](#), resulting from any commercialization by the Creator. The remuneration to FH shall be negotiable as to percentage and period of time.

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- b. Should FH decide not to retain its interest in the IP, FH may offer the Creator full rights in exchange for terms to be negotiated which could include reimbursement of any costs to date.

### 3.2.5 Use of Income Derived from IP

- a. FH shall use a portion of revenues from inventions to further advance research at FH. That portion of such revenue shall be recommended to the Chief Executive Officer by the VP Academic, Research and Clinical System Redesign, in consultation with the Chief Financial Officer.
- b. Revenue arising from the development of other types of IP shall normally be shared between FH and the developing department on a fifty-fifty basis, unless negotiated otherwise.

### 3.3 IP Arising Out of Education and Information Materials

#### 3.3.1 FH Rights

- a. The first "copyright owner" is, generally speaking, the author of the original [work](#). However, where a FH employee, privileged physician or contractor creates a work in the course of their employment with FH, FH is the first copyright owner, unless there is a specific agreement to the contrary.
- b. The unauthorized reproduction of [Education and Information Materials](#) produced by FH for the purposes of sale, rent, trade, or distribution for commercial use is forbidden as FH is the copyright owner of these materials. This includes education and information materials that may be available as a public document on the FH internet site.
- c. Where there are multiple authors of an original work (e.g. FH and another organization), there may be joint ownership of the copyright unless the parties have agreed otherwise.
- d. Upon request from a third party, FH may choose to allow reproduction of Education and Information Materials for commercial or non-commercial purposes.

The decision to allow reproduction for commercial purposes shall include evidence that the reproduction is in the public's interest, that it does not contravene FH policies or the B.C. Freedom of Information and Protection of Privacy Act, and that it is not at a cost to FH.

Reproduction for non-commercialization purposes may include cost-recovery.

- e. FH shall require a third party to withdraw or cease reproducing a work if that reproduction purports to be the official version and is: 1) not accurate; 2) considered to be misleading for any other reason (e.g. out of date material presented as current); or 3) for commercial purposes and is being done without a license agreement from FH.

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- f. The use of a [Copyright Disclaimer](#) [See [Definition of Terms](#)], which appears as a sentence or paragraph after the copyright notice and which sets out the terms under which the work may be used, modified and/or reproduced without the user first obtaining a formal license or assignment from FH may be used under applicable circumstances.
- g. A [Disclaimer of Liability](#) [See [Definition of Terms](#)] shall be included in the copyright disclaimer when there is a need to limit FH's exposure to liability and damages in the event that a harm or injury could be suffered as a result of a user acting, or neglecting to act, in a certain manner in reliance on the contents of an FH publication.

### 3.3.2 Prohibition on Use of FH Trademark

- a. No one shall use the FH trademark/logo in relation to the development or commercialization of IP without the permission of the Vice President Communications.

## 4. [PROCEDURES](#)

*Procedures may be amended by the Vice President, Academic, Research and Clinical System Redesign, the Vice President, Communications and Public Affairs, and the Vice President, Professional Practice and Integration, without further approval, provided the new procedures conform to the approved policy. Each sub-set of procedures initially approved by one Vice President, requires overall approval from the entire group of Vice Presidents.*

### 4.1 Administration

- a. Responsibility for the development and commercialization of any inventions arising from Research or work-related activities lies with the Vice President, Academic, Research and Clinical System Redesign.
- b. Responsibility for the development and approval of all patient care education and information materials lies with the Chief Nursing Executive and Vice President, Professional Practice.
- c. Responsibility for the development and approval of all general information materials for the wider public lies with the Vice President, Communications.
- d. Responsibility for the development and commercialization of business tools lies with the Vice President, Finance.

### 4.2 IP Arising Out of Research or Work-related Duties

#### 4.2.1 Disclosure and Assignment Report

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- a. A disclosure report shall be submitted by all researchers regarding their development of IP that meets the terms of this policy to the FH Research Office. The disclosure should be made before the details of an invention are included in any grant application. This disclosure report shall also assign rights of the IP to FH.
- b. The disclosure report shall include a description of the invention. Confidential information and know-how should be clearly defined and the invention must be adequately described and claimed in precise terms.
- c. The disclosure report shall be reviewed by the Vice President, Academic, Research, Clinical and System Redesign who shall recommend to the FH Executive whether or not development of the IP is viable. A preliminary examination shall be conducted in consultation with the New Business Development department to determine if a commercialization opportunity exists such that there is market feasibility. The VP Research may choose to authorize a market/commercial feasibility assessment if further expertise is required.
- d. The Creator(s) shall be notified within three months of receipt of the disclosure report whether or not FH will retain the rights to the IP.
  - i. Upon notifying the Creator(s) that FH wishes to retain the rights to the IP, a formal agreement shall be prepared by the Creator and submitted to the Vice President Academic, Research and Clinical System Redesign for execution within 10 business days. This assignment shall formally transfer 100% of the Creator's(s') right, title and interest in and to the IP to FH.
  - ii. In the event FH does not wish to receive an assignment of an invention, written notice shall be given to the Creator(s).
  - iii. The administrative supervisor for the Creator(s) shall be notified of the decision in writing.
- e. Within three months of receiving an assignment of the invention, reasonable steps to protect, develop, market, sell, license or otherwise dispose of the invention shall be taken under the direction of the Vice President, Academic, Research and Clinical System Redesign.

#### **4.2.2 Development of the IP**

- a. FH may choose to develop the IP in various ways, such as, but not limited to the following:
  - i. Undertake patent and /or licensing arrangements using the services of patent agents, lawyers and other consultants.

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- ii. Submit the proposal to a technology transfer or patenting corporation which has experience in evaluating inventions and obtaining patents on them, and which has the capability and facilities for introducing inventions and patents to public use.
  - iii. Assign FH rights in the IP to the Creator(s) by an agreement which may make provision for FH to receive a royalty on gross sales or shares in a company or other considerations as may be negotiated.
  - iv. In partnership with an existing business.
- b. The Creator may be consulted on the commercialization of the IP with respect to proposed patenting and licensing arrangements.

#### **4.2.3 Record Keeping**

- a. If a patentable invention might arise in the course of work on any project, laboratory and all other records should be kept in a bound (not loose-leaf) notebook and be dated, signed and witnessed, as a routine procedure.
- b. Critical and reserved information that is disclosed in proposals and grant applications must be marked with a copyright notice that sets out that the copyright is owned by FH and the year that the work was created, i.e. © Fraser Health Authority, 2007.

#### **4.2.4 Confidentiality**

- a. Other employees members and/or privileged physicians responsible for work which might give rise to a patentable invention should ensure that no one associated or familiar with the material involved releases any unauthorized information. If appropriate, those associated with such a project may be asked to sign a brief confidentiality agreement to this effect.

#### **4.2.5 Accounting**

- a. FH shall keep full and complete records and books of account with respect to all gross revenues, direct costs and net proceeds in connection with each invention.
- b. All such books and accounts relating to an invention shall be made available to the Creator and other parties, as applicable, on reasonable notice in order to review the revenues received and costs claimed with respect to an invention.
- c. An accounting shall be made annually at a minimum to the FH Executive.

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### 4.3 IP Arising Out of Development of Education and Information Materials

#### 4.3.1 Copyright Notice

- a. While copyright does come into existence automatically, each original FH work shall be marked with a basic copyright notice: © Fraser Health Authority, year of first publication (e.g. 2007).  
 “©” is the internationally recognized symbol for copyright, “Fraser Health Authority” is the name of the copyright owner, and “year of first publication” refers to the first year in which the work, in its current form, was published.
- b. This notice shall be displayed in such a manner and location as to give reasonable notice to users that FH holds copyright in the work. If the work can logically be broken into several pieces, the copyright notice should appear on each piece. If the work would normally be viewed as a whole, than a single copyright notice shall suffice.
- c. It is not necessary to register copyright with the Canadian Copyright Office. However, in cases where it is felt appropriate to register FH’s copyright, the VP Communications shall be consulted prior to such registration. The benefit of registration of copyright is that the Copyright Office will send FH a certificate evidencing FH’s ownership of the copyright. Such a certificate can be a useful tool to prove FH’s ownership if another party uses the work without FH’s permission. Upon decision that it is appropriate to register the copyright with the Copyright Office, the FH Communications and Public Affairs department will process the registration.
- d. If a Third Party wishes to reproduce a work or a portion of a work for non-commercial purposes, the third party must send a completed Copyright Permission Request Form to FH Communications and Public Affairs.
- e. If a Third Party wishes to reproduce a work or a portion of a work for commercial purposes, the Third Party must contact FH Communications and Public Affairs to obtain a license agreement. A fee and/or royalty shall be charged unless waived at FH’s discretion.
- f. FH shall refuse permission to reproduce a work or a portion of a work if that reproduction:
  - is not in the financial or public interest of FH;
  - does not comply with the policies of FH, or;
  - is not consistent with the Freedom of Information and Protection of Privacy Act or any other applicable legislation.

#### 4.3.2 Copyright Disclaimers

- a. A disclaimer may be appropriate for use under the following conditions when FH wishes to control activities related to the use, modification or reproduction of the material(s), for example:
  - i. permit users to engage in certain activities;

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- ii. require users to obtain a license from FH prior to engaging in certain activities;
- iii. prohibit users from engaging in certain activities;
- iv. retain or remove FH's copyright and other proprietary notices from any reproduction of the work; and
- v. whether it is appropriate and practical to include a copyright disclaimer (e.g. is there sufficient space to include one and is it needed?).

b. See [Copyright Disclaimer Examples](#) for samples of approved wording.

#### 4.3.3 Disclaimer of Liability

a. The need for a disclaimer of liability should take into account the nature of the publication and its intended audience. For guidance with respect to making this determination refers to [Disclaimer of Liability Guidelines](#) .

#### 4.4 Contracts

- a. All contracts with non-FH individuals or corporations external to FH whom FH may hire to carry out work on a contractual basis, as for example, an independent contractor or a contracted services employee shall specify that FH owns the copyright in any original work(s) or IP created by the contractor(s) in the course of carrying out his/her/their contractual duties. The contractor, contractor's employees and subcontractors shall be required to waive any rights over the works or IP.
- b. The FH signatory on the contract shall be responsible for bringing forward any IP arising out of the contractor's work that should be evaluated to determine if the IP should be protected.

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## 5. Definitions and Terms

### **Affiliated Researcher**

An affiliated researcher is an individual who does not have a direct relationship with FH by virtue of employment or being engaged as a privileged physician but who has met specific requirements for applying for this status and who has been granted this status by the Vice President Academic, Research and Clinical System Redesign.

### **Assignment**

Assignment means a transfer of rights in IP and is a legal document or process which transfers intellectual property to the institution, and which is recorded in the Patent Office.

### **Commercialization**

Commercialization means necessary activities undertaken in order to make use of the IP with the goal of financial return which is over and above that of simple cost recovery. Commercialization can include assignment, licensing, manufacturing or production of IP as well as the protection of IP, including, but not limited to, obtaining patent protection and copyright registration.

### **Confidentiality/Non-disclosure Agreement**

An agreement that provides evidence of the receiving party's understanding of the confidential nature of the information and expresses in written form its obligation to keep the information in confidence.

### **Copyright**

Copyright is a statutory right that is governed in Canada by the 'Copyright Act'. Copyright means the sole right of the creator or subsequent copyright holder to produce or reproduce the work or any substantial part thereof in any material form whatever, to perform the work or any substantial part thereof in public or, if the work is unpublished, to publish the work or any substantial part thereof.

Any original literary (including software), dramatic, musical, or artistic work qualifies for copyright protection. With the possible exception of a work that is a compilation of data, originality requires that the work originate with the author, rather than it have any particular merit or novelty.

If the author is a Canadian citizen or a citizen of a country with whom Canada has a treaty governing reciprocal copyright interests, or if the work is first published in Canada or such country, then copyright arises automatically, without the need for registration or other legal formality. Among the works protected by copyright are books, articles, sheet music, illustrations, photographs, motion pictures, works of sculpture and computer programs. Copyright protects the form of expression rather than the idea or

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content expressed. Copyright protection includes the right to translate or record a work as well as the right to transmit the work by telecommunication. The Copyright Act also creates "moral rights", which include the right of an author to be associated with the work and to prevent the distortion or modification of the work.

Only the owner of the copyright is allowed to produce or reproduce the work in question or to permit anyone else to do so. The author of a work is generally the first owner of copyright. However, if a work is created in the course of employment, the author's employer is the first owner of copyright. Ownership of copyright for a work created by an independent contractor or consultant will depend on the terms of the contract between the parties. Copyright protection in Canada lasts for the life of the author plus fifty years; it also extends to other countries by virtue of international treaties, although the term depends on the national law of each country.

When a copyright owner permits someone else to reproduce an original work, but retains ownership of the copyright, this is known as granting a "**license**" to reproduce. A license may be granted subject to certain conditions being fulfilled (e.g. reproduction only for certain purposes, payment of royalties, requirement to acknowledge FH, etc.). When, however ownership of the copyright is transferred from one party to another, in whole or in part, this is known as an "**assignment**" of the copyright. Any license or assignment must be set out in writing in order to be valid.

### Copyright Disclaimer Examples

The following are examples of different types of acceptable copyright disclaimers:

Example #1: No reproduction or modification of the work without authorization

**Basic:** *"All rights reserved."* (Note: this is a simple, cover-all statement that is the most commonly used copyright disclaimer.)

- OR -

**Detailed:** *"All rights reserved. No part of this publication may be reproduced in any form by any photographic, electronic, mechanical or other means, or used in any information storage and retrieval system, absent written permission from Fraser Health Authority."*

Example #2: Reproduction permitted if not for commercial redistribution

*"The Fraser Health Authority ("FH") authorizes the use, reproduction and/or modification of this publication for purposes other than commercial redistribution. In consideration for this authorization, the user agrees that any unmodified reproduction of this publication shall retain all copyright and proprietary notices. If the user modifies the content of this publication, all FH copyright notices shall be removed, however FH shall be acknowledged as the author of the source publication."*

*Reproduction or storage of this publication in any form by any means for the purpose of commercial redistribution is strictly prohibited."*

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### **Creator**

Creator(s) is defined as a sole individual or group of individuals working collaboratively and/or cooperatively, who make, conceive, reduce to practice, author, or otherwise make a substantive intellectual contribution to the creation of IP. Creator includes the concept of “inventor” as used in the Canadian Patent Act, or “author” as used in the Canadian Copyright Act.

A person who works under the direction of another and does not contribute any original thought to the claimed invention, cannot and must not be named as an inventor.

The initial ownership of IP resides with the creator of that IP. However rights can be assigned to the Creator’s institution according to the policy of that institution.

### **Direct Costs**

Direct costs are defined as the reasonable costs attributable to commercialization of IP, less any applicable grants or other reimbursements received from other parties. These costs may include, but are not limited to, direct salary and benefit costs for personnel engaged in commercialization activities, direct costs of consumable materials and other reasonable expenditures for evaluating IP, obtaining and maintaining IP protection, preventing unauthorized use or infringement, legal fees, prototype development funds, negotiating and implementing licenses or other agreements with third parties.

### **Disclaimer of Liability**

A disclaimer of liability is a statement that is intended to limit FH’s exposure to liability and damages in the event that a harm or injury is suffered as a result of a user acting, or neglecting to act, in a certain manner in reliance on the contents of an FH publication.

Whether or not the courts will give effect to a disclaimer of liability depends on (1) whether the law permits the exclusion of liability in the particular circumstances, and (2) whether the act(s) or omission(s) that resulted in the harm or injury fall within the scope of the disclaimer. As a result, it is critical that the particular disclaimer of liability to be applied to an FH publication contain the appropriate language in light of the nature of the publication and its intended audience.

For example, the appropriate disclaimer of liability that should be applied to clinical practice guidelines intended for use by health professionals should address the issue of those health professionals blindly relying on the guidelines without reference to changing standards of practice, etc. On the other hand, the appropriate disclaimer of liability that should be applied to a health-related publication directed at educating the public should address the issue of individuals relying on the information as medical advice, rather than consulting their own physicians.

### **GUIDELINES FOR INCLUDING A DISCLAIMER OF LIABILITY IN FH PUBLICATIONS**

- 1. Determine the nature of your publication.**

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Does your publication contain guidelines or recommendations concerning appropriate clinical practice? Does your publication contain medical/health advice or recommendations? Does your publication contain information that could be construed as legal, or other professional advice? Does your publication comment on or critique a particular product, individual or practice? The level of risk involved for those adhering to or misunderstanding the advice/information provided should be considered.

**2. Determine the intended audience for your publication.**

The required wording of the disclaimer of liability to be included in a particular publication depends to a large extent on the publication's intended audience (e.g. the general public, health professionals, prospective employees, other health authorities, contracted health service providers, literacy level, culture and anticipated level of understanding).

**3. Choose the appropriate disclaimer of liability based on your answers to questions 1 and 2.**

In some cases, a disclaimer of liability may not be appropriate or necessary. The following are the recommended disclaimers of liability for various types of publications typically produced by FH.

**Disclaimer of Liability: Clinical Practice Guidelines and other FH Publications containing Clinical Advice directed at Health Professionals**

*"The information contained in this publication was prepared for use by employees of, and in facilities that are owned and operated by, the Fraser Health Authority ("FH"). While care has been taken to ensure the accuracy of the information as of the date of publication, FH makes no warranty, express or implied, as to accuracy, completeness or currency. New knowledge, new technologies, clinical and research data, and clinical experiences may provide sound reasons for adopting alternative clinical practices. The ultimate judgment regarding the propriety of any specific clinical practice must be made by the health professional in light of the circumstances presented by the patient."*

**Note:** This type of disclaimer of liability is designed to convey to the user that the guidelines/clinical advice do not purport to reflect all medical considerations, and should therefore not be relied upon to the exclusion of other considerations specific to the circumstances of a given case.

**Disclaimer of Liability: Patient Education Materials**

*"The information contained in this publication is designed to be a general reference for [insert description, e.g. falls prevention, advance care planning, etc.]. While care has been taken to ensure the accuracy of the information as of the date of publication, it is not intended to provide specific medical advice or replace the specific recommendations of a health care professional, nor is intended to act as a substitute for any prescribed treatment. The Fraser Health Authority is not responsible for any problems that may arise from the use or misuse of the information provided in this publication."*

**Note:** This type of disclaimer of liability is designed to convey to the user that the materials are not intended to replace the specific advice of a physician or other healthcare professional.

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**Disclaimer of Liability: Critical Publications (e.g. Pharmacy News)**

*"The opinions and viewpoints expressed [in this publication/in the articles included in this publication] are those of the authors and do not necessarily reflect the opinions or position of the Fraser Health Authority as an organization. The information provided herein is for discussion purposes only, and readers should not necessarily rely on the information without verification."*

**Note:** This type of disclaimer of liability is designed to protect Fraser Health from any claims that the material is defamatory in nature.

**Disclaimer of Liability: General**

*"This publication is intended to provide general information only, and should not be relied on as providing specific healthcare, legal or other professional advice. The Fraser Health Authority, and every person involved in the creation of this publication, disclaims any warranty, express or implied, as to its accuracy, completeness or currency, and disclaims all liability in respect of any actions, including the results of any actions, taken or not taken in reliance on the information contained herein."*

**Note:** Fraser Health creates a number of publications that are "operational" in nature, and thus do not necessarily contain clinical or medical advice, but may contain information that may be considered professional advice of a different nature (e.g. legal, financial, etc.). This type of disclaimer of liability is designed to be a "catch-all" where a publication does not easily fit in to one of the previous categories.

**Disclosure**

The disclosure is legally confidential if, when receiving the information, the receiving party personally understands and accepts a duty to keep the information strictly confidential. A disclosure to a colleague may or may not be considered confidential depending on the understanding between the parties.

Any printed publication in a newspaper, scientific journal or other written form available on an unrestricted basis, including abstracts of papers for a scientific meeting or degree theses, is considered a public disclosure, as is an oral presentation at a public meeting. Any rights to subsequent patent protection in Canada are lost under these circumstances [this does not apply in the United States].

Disclosure to an institution's office responsible for intellectual property does not invalidate the patentability of an invention and is held to be confidential. A disclosure in a grant application does not represent public disclosure in Canada; however reviewers would be exposed to the invention and could represent an unnecessary threat in this regard. In the United States, grant applications may be considered public documents under Federal Freedom of Information legislation.

**Education and Information Materials**

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These may include materials developed for the purposes of education and/or informing patients, residents, clients, the general public, Fraser Health employees, physicians and volunteers, and may include materials used by Fraser Health employees and physicians for teaching purposes, educational software, books, posters, brochures, fact sheets, workshops and related workbooks, articles, graphic materials (maps, photographs, drawings), videos and film, architectural models or other materials used for explaining concepts and providing information to said audiences.

### Gross Revenue

Gross Revenue means all income including royalty, lump sum payment, profit share or other forms of consideration actually received by FH arising from the sale, licensing or other disposition of an invention to a third party or creator. Revenue does not include funding for research projects by either not-for-profit granting agencies or commercial sponsors.

### Intellectual Property

Intellectual property is defined simply as any form of knowledge or expression created with one's intellect. It includes such things as [inventions](#), computer software, trademarks, literary, artistic, musical or visual works, '[Know-how](#)', as well as trade secrets, plant breeders' rights, integrated circuit designs and personality rights, such as the right to an image.<sup>6</sup>

[Patents](#), [trade-marks](#), [copyright](#), industrial designs and similar rights are referred to as "intellectual property". These rights are "property" in the sense that they are based on the legal right to exclude others from using the property and in that ownership of the rights can be transferred. The rights are "intellectual" in the sense that they protect intangible subjects, usually arising out of some form of human creativity.

Patents protect [inventions](#), such as machines, devices, methods and compositions of matter. Trade-mark rights protect words, designs, numbers, two-dimensional or three-dimensional forms, sounds or colors (or a combination of two or more of these elements) used to distinguish the products or services of one trader from those of others in the marketplace.

Copyright protects literary (including computer programs), artistic, musical and dramatic works. Related rights include trade secrets, industrial designs, integrated circuit topographies, plant breeders' rights, and personality rights such as the right to the image.<sup>7</sup>

An invention is deemed to be 'made' when it is first conceived or first actually reduced to practice.

### IP Management and Technology Transfer

<sup>6</sup> Intellectual Property Institute of Canada (IPIC), Downloaded from <http://www.ipic.ca/english/general/> and, Canadian University Intellectual Property Group. A Guide to Protecting Intellectual Property. Downloaded from <http://www.research.utoronto.ca/ipc/cuipg.html>

<sup>7</sup> Intellectual Property Institute of Canada (IPIC).

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IP management is defined as the identification, protection, promotion, and/or [commercialization](#) of IP.<sup>8</sup> Technology transfer is also used to refer specifically to the assessment/identification, protection, development, marketing and licensing of resulting technology to companies for commercialization.

### **Invention**

Invention as defined in Canada's Patent Act means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. For the purposes of this policy it is also taken to include computer software, research data and research tools, and all proprietary information, know how and trademarks related to any of these items. The invention may or may not be patentable.

### **License**

License/licensing includes a permission to use an intellectual property right within a defined time, context, market line, or territory.

### **Know-how**

A researcher may often also possess confidential know-how and experience to permit commercial optimization of a process or product, in addition to the information that must be disclosed when filing a patent application to enable others to reduce the invention to practice. Know-how can be licensed independently and a know-how license need not be restricted to the term of the related patent.

### **Patent**

A patent means "letters patent for an invention" and is a bundle of important, and potentially, economically valuable rights. It is a right granted by a national government, upon application, and in exchange for a complete disclosure of an invention. The disclosure is initially a confidential disclosure to the patent office which later becomes a non-confidential disclosure to the public at large. In Canada, a patent is obtained from the Patent Office which is a federal government agency.

A patent provides a patent owner [a patent application may be filed naming one or more inventors] with the exclusive right to manufacture, sell and use the patented invention for a limited period of time. Copyrightable items, scientific theorems or principles, methods of doing business or of playing games are not patentable. The preferred form of protection for software is by copyright because of the difficulty in meeting the novelty requirement.

By law, in order to be patentable, an invention must be novel [absolute novelty is required in that no patent can be obtained if the invention has been made publicly disclosed in any manner, anywhere in the

<sup>8</sup> Statistics Canada, Science, Innovation and Electronic Information Division; Survey of Intellectual Property Commercialization in the Higher Education Sector, 2005

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world], must have utility, and the invention must not be obvious to a person skilled in the field of the invention.

Similar rights extend to patent owners in most other countries around the world, where patent protection is obtained. In other words, a patent is necessary in each country in which the Creator wants protection. In return for the grant of these patent rights, the patent must provide full disclosure of the invention. This means a description of the invention in sufficient detail that anyone trained in the field in which the patent is directed would be able to practise the invention after reading the description. Patent rights are limited in time, in Canada to a maximum of 20 years from the date of filing of the first patent application [i.e. in Canada, protection is granted to the first to file, not the first to invent as in the case in the United States]. Patent applications are published 18 months after the initial filing date.

Patents are also a source of useful technical information available to the public (which otherwise would have been kept secret).

### **Remuneration**

Financial compensation which could include [Gross Revenue](#) and which may also include equity, (i.e. ownership of shares) in commercial ventures.

### **Research 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. This definition also applies to research that may not involve human subjects. Research includes:

- obtaining data about a living individual through intervention (e.g. a medical procedure) or interaction (e.g. an interview) with the individual, or the obtaining of private personal information about the individual;
- secondary use of data (e.g. information, such as medical records, collected for purposes other than the proposed research) that contains identifying information about a living individual, or data linkage through which living individuals may become identifiable;
- naturalistic observation, except the observation of individuals in contexts in which it can be expected that the participants are seeking public visibility;
- the use of human remains, cadavers, tissues, biological fluids, embryos or foetuses.

### **Trade-mark and Trade name**

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A trade-mark is a word, design, number, two-dimensional or three-dimensional form, sound or color, or a combination of two or more of these elements which a trader uses to distinguish his/her products or services from those of his/her competitors and serves to establish goodwill with the consumer. Almost every kind of company that operates a business uses a trade-mark of one kind or another to identify its products or services.

The difference between a trade-mark and a trade name is that the first is used with specific products or services coming from a single source, the trader, while the second identifies a company and its business as a whole. Words can be used interchangeably as both a trade-mark and a trade name. Use as a trade-mark will depend on the context of its use.

Trade-marks are registered for a renewable term.

## 6. References

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