



<b>Title:</b> Intellectual Property	<input checked="" type="checkbox"/> Policy <input checked="" type="checkbox"/> Procedure <input type="checkbox"/> SOP
<b>Category:</b> General <b>Dept/Prog/Service:</b> Research: Research Administration	<b>Distribution:</b> Organization Wide
<b>Approved:</b> President & CEO <b>Signature:</b>  <b>Approved:</b> Vice President, Research <b>Signature:</b> 	<b>Approval Date:</b> Sept. 1, 2015 <b>Next Review Date:</b> <b>Reviewed/Revised Date:</b> Sept. 2018

## 1. PURPOSE

- 1.1 The purpose of this statement of policy and procedure is to protect Intellectual Property rights developed by Researchers in connection with the Thunder Bay Regional Health Sciences Centre (the "Hospital") or the Thunder Bay Regional Research Institute (the "Institute"), and to ensure that standard procedures and guidelines are applied in the assessment and Commercialization of Intellectual Property.

## 2. POLICY STATEMENT

- 2.1 The policy provides a process for the evaluation, protection, and Commercialization of Intellectual Property and defines the expectations and responsibilities of Researchers, the Hospital, and the Institute as applicable. It is intended to encourage the creation of Intellectual Property, facilitate the Commercialization of Intellectual Property, and ensure that the proceeds from the Commercialization of Intellectual Property are distributed in a manner consistent with these goals and for the advancement of research at the Hospital and the Institute.

## 3. SCOPE

- 3.1 The Hospital and Institute will adhere to and enforce the policy and procedure outlined in this policy.
- 3.2 All Researchers are bound by the terms of this policy.

## 4. DEFINITIONS

**"Commercialization"** means activities undertaken to make use of Intellectual Property with the goal of financial return, and can include production, manufacturing and sale of goods or services, assignment and licensing of Intellectual Property rights, and activities related to obtaining protection for Intellectual Property including but not limited to patent protection, industrial design protection, and copyright protection. **"Commercialize"** and **"Commercialized"** mean the act of undertaking one or more of the foregoing activities.

**"Created"** means created, conceived of, reduced to practice, developed or authored by an individual, whether alone or with others.

**"Institute"** means Thunder Bay Regional Research Institute (TBRI). TBRI is a separate legal entity engaged in a Joint Venture Agreement with TBRHSC as the designated research arm of the

Hospital. TBRI will lead the review, protection, and development of all IP.

**“Hospital”** means the Thunder Bay Regional Health Sciences Centre (TBRHSC).

**“Intellectual Property”** means all intellectual property and industrial property rights and assets recognized by the laws of Canada or any other jurisdiction throughout the world, and all interests and protections that are associated with, similar to, or required for the exercise of any of the foregoing, howsoever arising and whether registered or unregistered, and includes without limiting the generality of the foregoing: (i) Inventions (whether or not patented or patentable), discoveries, new life forms, works of authorship, trade secrets, know-how, designs, software, and rights in relation to technology and technical information, (ii) rights arising from laws in relation to patents, copyright, trademarks, industrial designs, plant breeders rights, integrated circuit topographies, computer programs, trade secrets, know-how, and data sets, and (iii) all past, present and future causes of action and claims for damages and remedies arising from the violation of the foregoing.

**“Invention” or “Inventions”** 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 (s. 2, *Patent Act*, R.S.C. 1985, c P-4). Invention also includes subject matter that constitutes an invention or patentable subject matter according to the laws of any jurisdiction.

**“IDC”** is the Intellectual Property disclosure committee responsible for reviewing Intellectual Property disclosures that are filed, and providing insight on Commercialization, future initiatives and viability of the disclosed Intellectual Property. The IDC is Chaired by the VP Research (TBRHSC/TBRI).

**“Net Income”** means gross revenue from royalties, licensing and other income actually received from the Commercialization of the rights in Intellectual Property, less expenses, taxes and costs.

**“Professional Staff”** means those physicians, dentists (including oral and maxillofacial surgeons), midwives, and registered nurses in the extended class who are appointed by the Board of Directors of the Hospital and who are granted specific privileges to practice.

**“Researcher”** means anyone who participates in work, study, research or development activities at the Institute or Hospital using, in any way, facilities or resources owned, operated, rented, or administered by the Institute or Hospital, and/or funds of, or funds administered by, the Institute or Hospital, and includes, but is not limited to, employees, Professional Staff and individuals with scientific appointments in part or in whole at the Institute or the Hospital, research associates, research assistants, clinicians, technologists, trainees/students, and any person with temporary privileges (e.g. visiting researchers, affiliated scientists, etc.) who participate in work, study, research or development activities at the Institute or the Hospital.

**“Reviewer”** means an external body or organization that can provide review and input on the merit of intellectual property protection such as MaRS Innovation or a patent lawyer.

## **5. PROCEDURE**

### **5.1 Ownership**

- 5.1.1 Except as provided in section 5.1.6, the Institute shall own and Researcher shall assign all worldwide right, title and interest in Intellectual Property that is Created by Researcher.
- 5.1.2 Upon request, and without further consideration but at the Hospital's or the Institute's expense, Researcher shall;
- do such things and execute such documents as may be necessary or desirable to fully vest title in the Intellectual Property to the Institute, its successors or assigns;
  - do such things and execute such documents as may be necessary or desirable to obtain, register, and maintain the Intellectual Property in any and all jurisdictions; and
  - cooperate and assist the Institute and Hospital, and their respective successors or assigns, in the prosecution of any legal or administrative action or proceeding to defend or to enforce the Intellectual Property in any and all countries, including the furnishing of relevant evidence, documentation, and testimony available to Researcher.
- 5.1.3 Researcher shall disclose in writing to the Institute and the Hospital all relationships with, and obligations to, an individual or entity who may claim an interest in or a right to use Intellectual Property that is Created by Researcher. Such relationships and obligations include, but are not limited to, a cross-appointment, an employment or other service relationship with another institution, a contractual obligation to assign or license Intellectual Property to another individual or entity, an obligation to assign or license Intellectual Property in exchange for research grants or other funding, or an obligation to publish Intellectual Property or make Intellectual Property available for public use.
- 5.1.4 Researcher represents and warrants that s/he does not have any relationship with or obligation to an individual or entity who may claim an interest in or a right to use Intellectual Property that is Created by Researcher, other than as disclosed pursuant to section 5.1.3. Researcher shall not enter into a relationship with, or undertake an obligation to, such an individual or entity without first obtaining the written consent of the Institute. For greater certainty, Researcher may not accept any offer of financial support for the patenting, licensing, or development of Intellectual Property from a source other than the Institute without the prior consent, in writing, of the Institute.
- 5.1.5 At least 60 days prior to the termination of a Researcher's employment, appointment, or other relationship with the Hospital or the Institute (or where that is not possible, as soon as practicable thereafter), Researcher shall meet with the VP Research and the IDC to disclose the status of all projects and Intellectual Property involving Researcher. The VP Research and the IDC shall consider whether there is Intellectual Property with the potential to be Commercialized, and the Hospital and the Institute shall consider whether one or both of them has a continued interest in the project or in the Intellectual Property. Where the Hospital and/or the Institute have a continued interest in the project or in the Intellectual Property, it/they shall negotiate a written agreement with the Researcher that provides, at a minimum, an obligation by Researcher to assign Researcher's interest in Intellectual Property that is Created within 12 months following termination of the employment, appointment, or other relationship with the Hospital or the Institute (or within such other period as the Researcher and the Hospital and/or Institute agree) and that is, in any way, connected with a Researcher's employment, appointment or other relationship with the Hospital or the Institute, or related to scientific information made available to the Researcher as a result of such employment, appointment or other relationship. Unless the Hospital and/or Researcher agree otherwise, the allocation of revenues received by the Hospital or Institute from any Commercialization of such Intellectual Property shall be consistent with the terms of this policy including section 5.9, and shall constitute full and sufficient consideration for the assignment of all

Researcher's right, title and interest in same. Where it is determined that the Intellectual Property that is Created in the 12 months or other period following termination will be carried out at one or more other institutions, the Hospital and Institute may consider an ownership or licensing arrangement that reflects the relative contributions of the Hospital, the Institute and such other institutions to the Intellectual Property that is Created.

5.1.6 The Institute does not claim ownership rights to Intellectual Property that:

- a) the Hospital and/or Institute have, in an agreement with another party, agreed will be owned by that party;
- b) was Created by Researcher and disclosed in writing to VP Research (TBRHSC/TBRRRI) prior to Researcher becoming an employee or appointee of the Institute or Hospital, or otherwise commencing activities as a Researcher;
- c) consists of a Professional Staff's ownership interest in the copyright that exists in academic works (such as books, book chapters, manuscripts, journal publications, conference proceedings, presentations, educational/informational materials and scholarly articles) that were Created by the Professional Staff (but for certainty, such academic works remain subject to this policy, and Professional Staff shall abide by the terms of this policy in respect of such academic works, including the obligations in sections 5.3 and 5.4 regarding the disclosure of academic works that contain, refer to or may affect Intellectual Property with potential for Commercialization); or
- d) was Created by Researcher outside the normal course of duties at the Institute or Hospital, on his/her own time, without the aid of the Institute's or Hospital's resources, and that does not arise from or relate to research carried out at the Institute or Hospital, provided that such Intellectual Property is disclosed in writing to VP Research (TBRHSC/TBRRRI); (but this section 5.1.6 c) does not apply to Intellectual Property that is the subject of section 5.1.5).

## **5.2 Required Documentation**

5.2.1 It is the responsibility of the Invention Disclosure Committee (IDC) to ensure that all required documentation is signed and adherence to this Policy and Procedure is undertaken by all Researchers.

5.2.2 It is required that all Researchers maintain records of their research activities that are dated and kept complete, current, and safe. Upon request, Researchers shall make the original records available to the Hospital or Institute and/or provide copies at the Hospital's or Institute's expense.

5.2.3 Researchers must comply with the Hospital's document retention policy as amended from time to time.

## **5.3 Confidentiality**

5.3.1 Each of the Researcher, the Hospital, and the Institute shall use best efforts to prevent any disclosure of Intellectual Property that could compromise the value of the Intellectual Property or negatively affect the ability to obtain the broadest possible protection for the Intellectual Property, worldwide. For example, the value of discoveries and inventions (whether or not the subject of a pending patent application), trade secrets and know how is compromised by disclosure. Researchers must consult with the VP Research prior to any disclosure of Intellectual Property.

5.3.2 In situations deemed acceptable by the VP Research (acting on behalf of the Hospital and the Institution):

- Intellectual Property may be disclosed to those individuals who have a need to know for purposes of carrying out their obligations in connection with Intellectual Property development and who have signed the Institute's Non-Disclosure Agreement ("NDA"), but only to the extent

that disclosure is required to carry out those obligations, and only in accordance with the terms and conditions of the NDA;

- Intellectual Property may be disclosed with the prior written permission of the VP Research, but only to the extent permitted by the VP Research and only in accordance with the terms and conditions communicated by the VP Research;
- The VP Research may request additional information from the Researcher, and may consult with the Scientific Director and/or the IDC to determine whether Intellectual Property may be disclosed, and the terms and conditions that should apply to such disclosure.

For greater certainty, but without limiting the generality of the foregoing, Intellectual Property shall not be included in or discussed in connection with any grant application, proposal, publication or presentation without the prior written permission of the VP Research.

5.3.3 The confidentiality obligations relating to Intellectual Property as set out in this Policy do not in any way replace, diminish or relieve a Researcher from the Researcher's obligations to protect other confidential information (including where such confidential information is embodied in Intellectual Property), such as patient data and records, and the financial and business records of the Hospital and Institution, among other confidential information.

#### **5.4 Publication**

5.4.1 Academic works such as books, book chapters, manuscripts, journal publications, conference proceedings, presentations, educational/informational materials and scholarly articles are subject to this Policy.

5.4.2 At least 30 days before any proposed disclosure or publication of an academic work that contains, refers to, or may affect Intellectual Property with potential for Commercialization, Researcher must submit a description of the proposed disclosure or publication to the VP Research, together with a statement from the Researcher as to how the academic work contains, refers to, or may affect Intellectual Property with potential for Commercialization.

5.4.3 The VP Research may request additional information, including a copy of the academic work, or where that is not possible, sufficient information about the academic work to determine whether it contains, refers to, or may affect Intellectual Property with potential for Commercialization. The VP Research may include the Scientific Director and/or IDC in the review. Within two weeks of the initial submission, the VP Research will inform the Researcher if the academic work can be disclosed or published, and if so, any terms and conditions of such disclosure or publication. Such terms and conditions may include, among other things: that certain information must be removed prior to disclosure/publication, that disclosure/publication must be delayed in order to secure or protect Intellectual Property rights, and/or that the Researcher include appropriate copyright notices. For clarity, academic works with the potential to be Commercialized are subject to all of the procedures of section 5.

5.4.4 Annually each Researcher must submit a list of academic works Created by him or her, to the Hospital or to the Institute (based on primary affiliation), which lists are to be made available to the Vice President of Research or the EVP Medical and Academic Affairs upon request.

- Professional Staff may submit the list through the annual renewal of privileges.
- Nursing and Allied Health professionals may submit the list to their Professional Practice Head.
- TBRR staff or affiliates may submit the list to the Scientific Director.

## **5.5 Disclosure**

- 5.5.1 Researchers are bound to promptly disclose in writing all Intellectual Property that was Created as a result of work, study, research or development activities at the Institute or Hospital, or using, in any way, facilities or resources owned, operated, rented, or administered by the Institute or Hospital, and/or funds of, or administered by, the Institute or Hospital.
- 5.5.2 A Researcher shall disclose Intellectual Property by completing an Intellectual Property Disclosure Form and submitting it to the IDC, as soon as reasonably possible after the Intellectual Property is Created. If required, the Researcher will then meet with the IDC, or designate initially, to discuss and review the written disclosure provided.
- 5.5.3 The disclosure may be forwarded to a Reviewer for consideration, and to conduct any due diligence deemed appropriate.

## **5.6 Contributor Group**

- 5.6.1 It is important to identify the person or persons who contributed to or participated in the creation, conception, reduction to practice, authoring or development of Intellectual Property (the "Contributor Group"). As soon as possible (and at the outset of a project that might lead to the development of Intellectual Property, wherever possible), Researcher shall submit to the IDC a list of all possible members of the Contributor Group, as well as a lead member. It is to be assumed, unless otherwise identified, that the lead member is a Researcher at the Institute or Hospital as applicable. Researchers shall submit updated lists as required throughout the course of the project.
- 5.6.2 The IDC, with input from a Reviewer and/or Researchers as required, will determine the membership of the Contributor Group.
- 5.6.3 The Contributor Group is responsible for updating the IDC as to the progress and status of the Intellectual Property as soon as it changes.

## **5.7 Decision to Proceed**

- 5.7.1 The IDC, with the assistance of a Reviewer, will consider the marketability and commercial viability of the disclosure. This review period will not normally exceed forty five (45) days.
- 5.7.2 After the review period, the Reviewer will provide to the IDC a written report with feedback pertaining to the disclosure. MaRS Innovation has the option to take the lead role on Commercialization of certain types of Intellectual Property (the "Subject Intellectual Property"), or decline and defer to the Institute.
- 5.7.3 If MaRS Innovation chooses not to Commercialize and develop the Subject Intellectual Property, the IDC will perform an internal review of the Reviewer's report to determine the best path forward for the Institute.
- 5.7.4 A summary from the IDC of each disclosure and path forward will be provided for information to Executive Management Committee (EMC) of TBRR, Senior Management Council (SMC) of TBRHSC, and Researcher, as applicable.

## **5.8 Commercialization**

- 5.8.1 If MaRS Innovation exercises its option to Commercialize the Subject Intellectual Property, MaRS Innovation's Commercialization process will take effect. Researcher agrees to abide by MaRS Innovation's Commercialization process, and cooperate fully with MaRS Innovation.
- 5.8.2 If MaRS Innovation does not exercise its option, and the Institute decides to Commercialize the

Subject Intellectual Property, the IDC will manage the process. The IDC will also manage the process where the Institute decides to Commercialize any Intellectual Property that is not Subject Intellectual Property.

- 5.8.3 The Institute may Commercialize the Intellectual Property directly, or through a third party agreement. The Contributor Group may provide input into the Commercialization of the rights.
- 5.8.4 The IDC will use reasonable efforts to keep the Contribution Group aware of steps being taken to Commercialize the Intellectual Property that was Created by a Contribution Group, and will report all expenditures and revenue resulting from the Commercialization to the Researcher as well as EMC of TBRI and SMC of TBRHSC as appropriate.

## **5.9 Allocation of Revenue**

- 5.9.1 Where the Institute Commercializes the Intellectual Property, Net Income received by the Institute will first be used to defray all costs associated with Commercialization and the Commercialization process (including but not limited to legal costs) and may also be used to defray all or part of any costs related to the research and development of the Intellectual Property. The Hospital, the Institute and the Contributor Group shall negotiate and set down in writing terms regarding the allocation of Net Income that exceeds such costs, and corollary terms including a payment schedule, reporting obligations and audit rights.
- 5.9.2 The Hospital's and the Institute's position on such terms (including the allocation of Net Income) will be guided by a number of factors including the estimated value of the Intellectual Property, costs of research, development or the Commercialization process that were not or will not be recovered by the Hospital and the Institute, and the contributions of the Researcher. Illustrative examples of Net Income allocations are as follows:
  - i. 20-50% to the Contributor Group,
  - ii. 50-80% to the Hospital and Institute, to be allocated between them by the CEO and COO with input by the VP Research (including the potential for some portion to be directed to the research program from which the Intellectual Property arose, typically at no more than up to 20%)
- 5.9.3 Sections 5.9.1 and 5.9.2 do not apply in cases where one or more members of the Contributor Group have a relationship with, or obligations to, an individual or entity disclosed pursuant to section 5.1.3 (including Researchers holding primary appointments at an external institution). In such cases, the determination of rights and the allocation of revenues arising out of the Commercialization shall be subject to terms and conditions as agreed to between the Institute, the Hospital and the external institution, taking into account the external institution's obligations to one or more Researchers in the Contributor Group.
- 5.9.4 In the absence of an agreement with an external institution, the Hospital and the Institute will endeavor to negotiate Commercialization terms with the external institution, individual or entity. This determination shall be made jointly by the Vice-Presidents of Research or by their delegates.
- 5.9.5 The Hospital and the Institute shall endeavor to reach an agreement that reflects the external institution's, individual's or entity's share in: providing use of its premises to members of the Contributor Group, compensation paid to members of the Contributor Group, and any other contribution to direct costs of the project that resulted in the Intellectual Property, excluding grants from third parties.

### **5.10 Decision to Not Commercialize or Cease Commercialization**

- 5.10.1 In the event that the Institute decides not to pursue any Commercialization of the Intellectual Property, or decides to cease all Commercialization of the Intellectual Property, the Institute shall assign to the Contributor Group all rights to the subject Intellectual Property (provided that such assignment does not conflict with any agreement between the Hospital, the Institute and an external institution, individual or entity), subject to the following conditions:
- i. that any costs incurred by the Institute or the Hospital associated with Commercialization of the Intellectual Property and the Commercialization process (including but not limited to legal costs) and the research and development of the Intellectual Property, shall be reimbursed as a first priority of any future revenues that may accrue to the Contributor Group from any sale, licensing or other arrangement, disposition or commercial exploitation of the Intellectual Property; and
  - ii. the Institute and Hospital shall receive a total of 25% of the balance of any future Net Income that may accrue to the Contributor Group.

### **5.11 Dispute Resolution**

- 5.11.1 Any dispute arising under this policy that cannot be settled amicably between the Parties shall be submitted to the CEO of TBRHSC/TBRI.
- 5.11.2 If the matter cannot be resolved by the CEO it will be submitted to arbitration by a panel composed of one member nominated by each Party and one or two members (to ensure an odd number) selected by mutual agreement of the Parties' designated members. If the Parties' designated members cannot agree on the identity of the additional panel member(s), an application will be made to the court for the appointment of the additional member(s).
- 5.11.3 The panel's decision will be made by a majority of the panel members within thirty (30) days of its appointment. The decision shall be final and binding upon the Parties.

## **6. RELATED PRACTICES AND/OR LEGISLATIONS**

Intellectual Property Law

## **7. REFERENCES**

*Reviewed by BLG for legal input. – final November 2015*