



## GENERAL GUIDELINES FOR INTELLECTUAL PROPERTY POLICIES

Developed by the TAHSN Research (TAHSNr) Committee

Version Date: March 1, 2022

---

### PURPOSE

To provide common principles and guidelines to TAHSN institutions and their respective research institutes, as applicable (referred to as 'TAHSN institutions' in this document), to help guide the development and/or update of their individual Intellectual Property (IP) policies.

This document provides a set of guidelines that each institution is encouraged to consider as they develop or update their IP policies to facilitate general alignment.

Alignment in IP policies across TAHSN is key to transforming innovation into commercialization to the benefit of health outcomes for the region and country. Collaborations between institutions will be better served by having more aligned IP policies in both direction and terminology, as that would help facilitate mutually agreeable terms for inter-institutional agreements.

### BACKGROUND

In April 2021, the TAHSN Research (TAHSNr) Committee reviewed different IP policies across the TAHSN institutions and identified substantial differences which, in some instances, may interfere with collaboration efforts across TAHSN institutions. To address this, nominated research leaders from each TAHSN organization came together to form an official subcommittee of TAHSNr named the *Intellectual Property Guidelines Working Group*. This working group developed common principles and guidelines in the interest of improving alignment where appropriate and fostering collaboration.

### CONSIDERATIONS

This document applies specifically to research-driven intellectual property policy.

### ASSUMPTIONS

For the purposes of this document, it is assumed that:

- This document is designed to outline standard items that should be included when drafting/updating IP policies and developing processes for commercialization. There is, however, no requirement for uniformity of IP policies across TAHSN as such policies are dependent on the resources available to the individual TAHSN institution, institutional culture, and their priorities with respect to impact on society.
- TAHSN has a common relationship management policy that addresses how potential conflict of interest is handled with startups.
- Commercialization support is a service that the institution provides for its operating units, employees, trainees, researchers and physicians for the benefit of all stakeholders, and in order



to maximize the impact of the institution's research outcomes for both the institution itself and society as a whole.

## **GUIDING PRINCIPLES FOR IP POLICIES**

**The following are principles that TAHSN institutions should address in their IP policies as applicable.**

- **Recognition of the value of commercialization**
  - Commercialization of research discoveries is often required in order to positively impact the health of both local and global populations. TAHSN institutions will act to protect IP and support mechanisms that lead towards their development into practical products, services, and practices.
  - Commercialization of IP can bring financial returns to the organization which further supports its research and academic mission. TAHSN institutions will act to receive fair and reasonable value for the IP that they create and contribute towards supporting its commercialization.
  - Given the importance of commercialization support to the institution and its community, institutions need to make decisions on:
    - Developing policies, procedures and guidelines to support the process of commercialization
    - The appropriate level of resources to support commercialization
- **IP ownership** – IP is an asset of the institution and needs to be managed and stewarded by the institution.
- **IP policy management** – A designated department/individual within the institution will be responsible for managing and/or overseeing all matters related to the organization's IP including review and receipt of IP disclosures, management and filing of appropriate IP-related registrations (patents, copyrights, industrial designs), commercial licensing or provision of IP rights to external partners or in some cases to its internal inventors, and the receipt and distribution of any revenues from the licensing or other commercial disposition of the institution's IP.
- **Disclosure and related obligations** – The institution's personnel must disclose to the designated department/individual all work products and services that have potential to create IP for the organization. It must be done in a timely and thorough manner, prior to any public disclosures or presentations, and with all supportive scientific and related information included. This obligation applies to the outputs and/or outcomes from both research-related activities (e.g. manuscripts submitted for publication or abstracts for presentation) and other non-research related activities with IP potential (e.g. hospital/patient management software, clinical trial questionnaires).
- **Dispute resolution** - In the event of any dispute arising under the IP policy, there will be an initial attempt to resolve it by the appropriate resolution process. If a resolution is not achieved, the dispute will be escalated to the organization's Vice-President (VP) of Research or designate.



- **Recognition of inventorship and other contributors to IP** (*Please see Appendix B below for examples*) – Institutions will develop mechanisms to appropriately recognize and value both the inventors of IP and those that contribute to the creation of value around IP.
  
- **Institutional Works and Discovery Works** (*Please see Appendix A below for examples*) – Institutions should consider distinguishing between inventions and contributions to IP that are created through either Discovery Works or Institutional Works, as per the following definitions:
  - **Institutional works:** All tangible materials, work products and services, outcomes, and results from the institution - which may include IP - that are:
    - Developed under specific institutional direction, or otherwise in the normal course of carrying out assigned responsibilities, duties or tasks of employment **or** For which discrete creator(s) cannot be attributed, or resulting from contributions over time by multiple contributors **or**
    - Developed by persons hired for a specific purpose (e.g. consultants, contract engineers, software developers)
      - Examples of Institutional Works under the above activities include but are not limited to: manuals, reports, processes, software, devices, programs or services, databases, clinical data, tissue/sera biobanks and reagents, whether or not such works are subject to IP protection.
  - **Discovery works** – All tangible materials, work products and services, software and algorithms, and outcomes and results - which may include IP – and are developed by institution personnel arising from independently conceived and self-directed:
    - Fundamental experimental research **or**
    - Technology development activities **or**
    - Analogous research activities
  
- **Reimbursement pre-revenue distribution** (*Please see Appendix C below for examples*) – Prior to any distribution, use or allocation of revenue under this policy, the institution shall first be reimbursed as per the institution's reimbursement guidelines.
  
- **Revenue distribution** (*Please see Appendix D below for examples*) – Institutions will share a component of revenue received that arise from commercialization of Discovery Works IP with inventors and/or contributors. Institutions should work towards a common revenue sharing framework to help facilitate inter-institutional agreements.
  
- **Research contracts & other agreements** – No research contract should be entered by any institution personnel with any research partner unless it is documented in writing and signed by the VP, Science & Research (or designate) and as further mandated in other relevant policies of the institution.
  
- **Institutional use of commercialization revenue** – Revenue from research-driven commercialization should be used by the institution to further support the overall research and commercialization mission, and according to the overall needs of the institution.



- **Securities** (*Please see Appendix E below for examples*) – TAHSN institutions should strongly consider establishing a policy and practice on the management of Securities.
- **Trademarks & Official Marks** (*Please see Appendix G below for examples*) – Each institute is to outline their process for approvals pertaining to trademarks and the use of the name or logo of the institution in any advertising, promotional, endorsement or sales material in any medium.
- **Equity, Diversity, Inclusivity (EDI)** – Institutions will apply EDI principles in all policies, practices, and supporting activities related to IP management and commercialization.
- **Inter-institutional Relationships**
  - The parties will outline a clear notification process when there are inventors/creators from multiple institutions and a disclosure is made to one institution.
  - The parties shall negotiate and determine who will lead the commercialization (refer to the University of Toronto (UofT)-Hospital Affiliation Agreement for further details).
  - The parties shall enter into an inter-institutional agreement that provides details of the relationship including but not limited to:
    - Who will be the lead party responsible for legal protection of the IP and its commercialization
    - How commercialization expenses will be shared
    - How proceeds will be divided among the parties, etc.
  - The institution updating/developing its IP policy should review its current UofT-Hospital Affiliation Agreement as a part of the process.
- **Startups** (*Please see Appendix F below for examples*) – This is a rapidly evolving pathway in the activity of commercialization. The institution should provide clear processes/approaches, relationships and terms between founders and the institution(s). In establishing such processes/approaches, best practices should be taken into consideration.
  - Each TAHSN institution will align its startup strategy with both its IP policy and conflict of interest (or relationship management) policy as outlined in its UofT-Hospital Affiliation Agreement
  - Each TAHSN institution should outline resources that are available to them in their guidelines for reference, as all institutions will have different internal and/or community resources to support startup activity.
  - The *'Recognition of the value of commercialization'* principle listed above (page 2) is to be incorporated into the institution's processes/approaches for startups
  - Given that researchers in TAHSN institutions including UofT may be in conflict of interest if they are involved with a startup, all researchers need to declare and manage any potential conflict as per institutional guidelines.
- **Open science** – Open Science strategies and commercialization are not mutually exclusive or 'alternate' approaches. IP protection should be encouraged where it is required by the market as a way for optimal advancement, dissemination, and scale of viable innovations to be delivered to global patient populations (in case of health research). IP protection and



commercialization do not necessarily contradict the principles of open science and it is indeed possible to achieve both by implementing appropriate strategies.



## APPENDICES

The sections below provide examples of how some TAHSN institutions address the guiding principles in their individual IP policies. Some guiding principles will have more examples than others as this depends on how many TAHSN IP policies contain the principle in question.

Appendix A - Institutional works and discovery works.....	7
Appendix B - Recognition of inventors vs. contributors .....	8
Appendix C - Reimbursement pre-revenue distribution .....	10
Appendix D - Revenue distribution formula .....	10
Appendix E – Securities.....	12
Appendix F – Startups .....	13
Appendix G - Trademarks & official marks .....	13



## Appendix A - Institutional works and discovery works

### **SickKids:**

- Institutional work(s): all tangible materials and work product generated by Creators or other persons hired, commissioned, retained or otherwise engaged by the Hospital for a specific purpose and under specific institutional direction. Examples of Institutional Works include, but are not limited to, manuals, reports, processes, software, devices, programs or services whether or not such works are subject to intellectual property protection.

### **University Health Network (UHN):**

- Research (aka discovery) works: Tangible materials and any other outcome, output, result and matter developed by UHN personnel arising from independently conceived and self-directed fundamental experimental research or technology development activities, or other basic discovery or analogous research activities, and which are not institutional works or traditional academic works. Research works may include IP consisting of patent(s), copyright(s), or both.
- Institutional work(s): All tangible materials and any other outcome, output, result and matter developed by (i) UHN personnel under explicit institutional direction or instruction, or which otherwise arise in the normal course of carrying out assigned responsibilities, duties or tasks of employment; (ii) UHN personnel and for which such development cannot be attributed to discrete creator(s), or is resulting from simultaneous or sequential contributions over time by multiple contributors; (iii) UHN personnel in the normal course of carrying out assigned responsibilities, duties or tasks of employment pertaining to UHN's educational and training activities, including, without limitation, all educational and training information, manuals, and associated tools and materials (whether in written, electronic, audio-visual, multi-media or other form or format); or (iv) persons hired by UHN for a specific purpose (e.g. consultants, contract engineers, software developers). Institutional works may include IP consisting of patent(s), copyright(s), or both.

### **UofT:**

Institutional work(s) (taken from UofT Inventions Policy):

- Invention made in the course of activities performed pursuant to direction given by a faculty or staff member of the University specifically with the object of making such an invention;
- made by an Inventor who is a member of the administrative and support staff of the University as a result of activities covered by the Inventor's contract of employment; or,
- specifically commissioned by the University under a written agreement in which the Inventor assigns ownership of the Invention to the University; and the disposition of all rights in, and the allocation of revenue from, such



## Appendix B - Recognition of inventors and/or creators vs. contributors

**Centre for Addiction and Mental Health (CAMH):** CAMH policy defines 'creators' as CAMH personnel who:

- a) for the purposes of patent, make(s) or develop(s) an invention or
- b) for the purposes of copyright, make creative or authorship contribution

### **UHN:**

The policy includes "creators" as personnel identified as authors, inventors, or, in the case of non-patentable/non-copyright IP, those individuals making a significant intellectual contribution. Creators (not just inventors) are eligible to share in commercialization revenue under the IP policy.

- **Creator(s):** UHN personnel identified as (i) an author, (ii) an inventor, or (iii) in respect of licensed UHN IP which is neither patentable or copyrightable subject matter, a significant intellectual contributor to the development of such UHN IP, but only where such development is not a routine or known practice or activity.
- **Inventor(s):** Any individual (which includes any UHN personnel) who makes an inventive contribution to the creation and/or development of patentable IP (as determined in law).

### **UofT:**

"Inventor" or "Inventors" means any person, including any member of the academic staff, librarian, administrative staff, postdoctoral fellow, visitor, student, or person holding an academic appointment at the University, who makes or develops an Invention using, in any way, facilities owned, operated or administered by the University and/or funds of, or funds administered by, the University.

An Invention means:

- (a) "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" [Patent Act, R.S. 1985, c. P-4, s. 2], whether or not patentable;
- (b) computer software under section 2.6 of the University's [Copyright Policy](#);
- (c) research data or research tool, including, without limitation, biological material and other tangible research material; and,
- (d) proprietary information, know how, trademark related to any of the foregoing items; and includes all legal and equitable rights relating to such property.

UofT includes a contributor section in the invention disclosure form but contributors are not addressed in the Inventions Policy. The sole purpose in including the information in the invention disclosure form is to clarify who has inventive rights to the IP and/or if there is an associated pre-existing agreement with the contributing parties. If there is an existing agreement it is considered in discussions with the external parties. UofT has not developed guidelines for sharing with contributors. It is considered in a case by





case basis with input from the inventors. If agreement cannot be reached, contributors are not granted a portion of invention revenue. If there is an agreement in place, but there is a dispute, the matter goes to arbitration.



## Appendix C – Reimbursement pre-revenue distribution

**UHN:** Prior to any distribution, use or allocation of revenue under this policy, the institution shall first be reimbursed for the following (in order of priority):

- Institution's out-of-pocket costs and fees associated with securing, maintain and enforcing IP protection; commercialization of the intellectual property; management and liquidation of securities; and making, shipping, or distributing material
- Institution's defined investments, costs and expenses related to defined technical/scientific development required for commercialization or other commercial development activities of the licensed IP, subject to approval by the VP of Science and Research
- Institution's costs incurred in a dispute resolution process conducted further to this policy

**UofT:** Net Revenue is distributed annually

- "Net Revenue" means the royalty, licensing and other income or equivalent financial return, including the proceeds of disposition of share capital or other financial instruments, received from the assignment or licensing of the rights in an Invention, less legal and other fees incurred directly in the process of establishing and maintaining the legal protection of those rights

**Under the Affiliation Agreement between UofT and the hospitals,** the only deductions to be made are: "legal and other fees reasonably and actually incurred directly in the process of establishing and maintaining the legal protection of those rights." For IIA's between the Parties, this implies an expectation that only patent related costs are deducted before revenue distribution between the institutions *unless otherwise agreed*.



## Appendix D – Revenue distribution formula

*It is recognized that there would be benefit to discussing – amongst the TAHSN institutions - the distribution of the institutional portion of revenues.*

**Baycrest, North York General Hospital, SickKids, Unity Health Toronto:** 50% to inventors and 50% to organization

- **UHN:** Net Revenue from Research Works are 50/50 between UHN/Creators. Institutional Works = 100% UHN.

**CAMH, Holland Bloorview, Sunnybrook:** 40%, 40%, 20%

- **CAMH:** Where CAMH chooses not to commercialize IP, creators can request assignment of IP and royalty agreement --> 25% net revenue to CAMH
- **Holland Bloorview:** 40% Inventors; 40% Organization; 20% Department/program
- **Women's College Hospital:** Net revenue from IP is shared with inventor, generally on an equal basis (with WCH, not specified whether would go to department or not). Where WCH chooses not to commercialize IP, creators can request assignment of IP and royalty agreement --> 25% net revenue to WCH

**Sinai Health:** 40% to inventors 60% to hospital/institute; of the 60% for Inventions arising out of research conducted at the LTRI, 40% is to be paid to the LTRI, and 20% is to be paid to a special projects research fund administered at the discretion of the Director of Research with priority given to the area of research of the Invention; of the 60% for Inventions arising out of research conducted at a clinical department of the Hospital, 40% is to be paid to a Hospital-wide fund for research and education administered by the Hospital Administrator, and 20% is paid to a special projects research fund administered at the discretion of the Chief of Service of the department in which the Invention arose with priority given to the area of research of the Invention.

**UofT:** If owned by UofT, 60% inventors, 20% Organization, 10% Department, 10% Division. The institutional proportions change depending on net revenue. If net revenue exceeds \$500K, institutional proceeds go to the Connaught Fund to support research programs.

**Trillium Health Partners:** does not cover revenue and revenue distribution; only addresses ownership rights (100% to physician inventor)



## Appendix E – Securities

### **UHN:**

- All publicly traded equity received by UHN in the course of commercializing UHN IP, whether directly or indirectly, shall be held by UHN Treasury under the authority of the chief financial officer (CFO). Such securities will be managed according to procedures to ensure that decisions are made at arms-length from creator(s) and UHN staff involved in the licensing of the UHN IP. The proceeds from the sale of securities will be treated as gross revenue derived from UHN IP, and will be distributed according to this policy. UHN's Treasury does not hold private equity.
- For purposes of clarity, only revenue arising from the liquidation of securities which was specifically received by UHN as identified consideration for the licensing or sale of particular UHN IP will be distributed in accordance with this policy.

### **UofT:**

- All publicly traded equity received by UofT in the course of commercialization is managed by an external broker (e.g. Morgan Stanley). The securities are managed according to standard procedures to ensure decisions are made at arm's length.
- Private equity is managed as per the company's shareholder agreements which often include provisions such as drag along rights, voting rights, etc.
- Only revenue arising from the liquidation of securities which was specifically received by UofT as consideration for the licensing or sale of UofT IP will be distributed in accordance with the Inventions Policy. All securities granted under the provision of a license or sale of UofT IP are managed by the institution. Inventors who are also founders waive their rights to revenue received from the institutions liquidation of securities.



## Appendix F – Startups

### UHN Spin-out/Company Creation:

UHN's Technology Development & Commercialization (UHN TDC) will participate (on behalf of UHN) in the creation of UHN "spin-out" and any other newly created companies which license or acquire UHN IP. Such participation may include:

- The negotiation of an appropriate UHN equity stake in the UHN "spin-out" or newly created company (each a "NewCo"),
- The terms and conditions pertaining to the acquisition or licensing of the UHN IP to the NewCo,
- NewCo corporate documents,
- UHN personnel involvement in management and/or governance,
- The use of UHN space or facilities by NewCo,
- Visiting scientist agreements
- and/or any research contract between the NewCo and UHN.

All company creation activities by UHN personnel which involve the use of UHN IP (whether or not such UHN personnel are creator(s) of such IP) and/or UHN resources must be negotiated with UHN TDC and approved in writing by the EVP, Science & Research. All such company creation activities, in addition to any further contemplated contractual or other arrangement between NewCo and UHN, must be disclosed to the UHN Compliance Department for review and assessment in accordance with relevant UHN policies (i.e. Conflict of Interest policy, Conflict of Interest of Research Personnel policy).

Nothing in this policy restricts a creator of UHN IP licensed to a NewCo from entering into a contractual relationship with such NewCo in a personal capacity (e.g. consulting agreement) for compensation involving fees and/or NewCo equity. However, any such contractual relationship will be at the exclusive discretion of the NewCo, and will remain subject to all relevant UHN policies.

An exception to the "50/50" distribution for Research Works may arise in certain circumstances, such as when creator(s) receive "founders" equity in a UHN "spin-out" company (a "NewCo"). In such cases, UHN TDC will assess the extent of such "founder" shareholding and the further role of the creator(s) in the NewCo (including the mitigation and management of any potential conflicts of interest) to determine the scope of any further entitlements under this policy. As such, UHN TDC may determine that such creator(s) should not receive some or all of the creator(s)' personal share of net revenue. For example, creator(s) with a significant financial interest and/or managerial role in the NewCo may be required to forfeit in advance some (or all) of their individual personal entitlements under the policy. UHN TDC shall make a recommendation in this regard to the EVP, Science & Research, who shall make a final determination. In the event of any such revenue forfeiture, UHN will retain the forfeited revenue.

### UofT:

UofT distinguishes between UofT lead start-up and inventor/founder lead start-up. For an inventor/founder lead start-up, resources are available through [UofT Entrepreneurship](https://entrepreneurs.utoronto.ca/) (<https://entrepreneurs.utoronto.ca/>) programs. There are two Entrepreneurship programs; UTEST and H2i (<https://h2i.utoronto.ca>), which are also accessible to companies based on hospital intellectual property.

The UTEST program offers;



- Mentoring and business strategy consultation
- Incubations space (currently office space only)
- Access to corporate lawyers, investment capital and pitch competitions.
- Opportunity for investment from the Connaught Fund (UofT IP based companies only)

IPO and/or UTEST representatives will validate the contribution of inventors and/or founders in the company vs. their contribution to the invention prior to an investment event. This will help define the founder share allocation prior to the first investment

UofT lead start-ups are managed in collaboration with TIAP under their Venture Builder program.

For both inventor lead or institution lead start-ups IPO personnel may be an observer on the Board. If warranted, either IPO or UTEST will arrange for NewCo corporate documents. Under no circumstances are UofT/IPO personnel involved in the management of the NewCo. IPO is available to mentor interim management which generally consists of a grad student, post-doc, research associate, MBA student, TIAP personnel and/or external founders. IPO's role is to act on behalf of UofT and negotiate an appropriate UT equity stake, terms and conditions of the license, finalize research contracts and visiting scientist agreements. A separation of company and institutional representation is essential for preventing conflict of interest.

UofT has also developed prerequisites and a process for licensing IP to a start-up. Please see attached document. In short, a start-up must demonstrate that they can be responsible stewards of the institutional intellectual property. Due diligence on the start-up is required.

Conflict of interest is managed through the Conflict of Interest Policy for Academic Staff.



## Appendix G - Trademarks & official marks

**CAMH:** The assumption in the current version of the guidelines document is that any new trademark application for a new product created at the institution should be vetted by Public Affairs. This may not be the case for each TAHSN institution, at CAMH the approval is done by Legal and Public Affairs.

**UHN:**

- UHN personnel shall obtain written approval from the appropriate UHN Public Affairs office for the use of the name or logo of UHN, a UHN member hospital, or a UHN associated research or teaching institute, in any advertising, promotional, endorsement or sales material in any medium.
- However, it is generally acceptable (and therefore requires no further approval) for UHN personnel to use the name and logo of UHN, a UHN member hospital, or a UHN associated research or teaching institute, in a traditional academic works or for other academic-related reasons to identify the association of the UHN personnel with any of the aforementioned entities.
- No trademarks shall be applied for, or registered, in respect of any product, service or any other activity associated with UHN, a UHN member hospital, or a UHN associated research or teaching institute, without prior permission from UHN's public affairs office. Unless specifically agreed to otherwise by UHN, any trademark associated with any product, service or any other activity associated with UHN shall be owned by UHN.

**Unity Health Toronto:** Approval rests with the Public Affairs team; consultation with Unity Health's General Counsel may be required.

**UofT:** handled by Trademark Licensing Office (<https://trademarks.utoronto.ca/>)



## APPENDIX H – Intellectual Property Guidelines Working Group Members

This section lists the members of the Intellectual Property Guidelines Working Group who led the development of this document.

- Baycrest – Jean Lazarus, Director of Research Operations
- Baycrest – Ran Manor, Director of Innovation
- Centre for Addiction and Mental Health - Klara Vichnevetski, Director, Industry Partnerships and Technology Transfer
- Holland Bloorview - Sharon Wong, Director of Commercialization
- Hospital for Sick Children - Ihor Boszko, Executive Director of the Industry Partnerships & Commercialization team
- Michael Garron Hospital (Toronto East Health Network) - Kristen Currie, Manager of Research and Innovation
- North York General Hospital - Michael Wood, Director of Research and Innovation
- Sinai Health - Darlene Homonko, Director of Technology Transfer and Industry Liaison
- Sunnybrook Health Sciences Centre - Raphael Ronen, Director of Business Development
- TAHSN Secretariat - Selma Al-Samarrai, TAHSN Advisor
- Trillium Health Partners - Delilah Ofosu-Barko, Director of Research Operations
- Unity Health Toronto - Samar Saneinejad, Senior Director, Strategy and Commercialization
- University Health Network – Mark Taylor, Director of Commercialization
- University of Toronto - Jennifer Fraser, Director, Innovations
- University of Toronto - Paul Santerre, Baxter Chair for Health Technology and Commercialization, UHN-Techna
- Women's College Hospital - Katharine Schwartz, Director of Research Operations