

Boston Children's Intellectual Property (IP) Policy

Boston Children's Hospital promotes the development of research and clinical discoveries and innovations in order to benefit the public, to encourage inventorship, and to build our research endowment.



*Guidance Documents
available on [TIDO website](#)*

Updated 4/09/2018



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

Outline

- Overview of Innovation Support at BCH
- Context for IP Policy
 - Basis for Intellectual Property (IP) Policy
 - Bayh-Dole Act
- Specifics of the IP Policy
- What you need to do
- Questions



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

Support for Innovation at Boston Children's Hospital

Technology & Innovation Development Office (TIDO)

- Building partnerships to increase the impact of BCH research on patient health
 - Identify research with commercial potential
 - Build commercialization strategy (marketing, IP protection)
 - Fund proof-of-concept (Technology Development Fund)
 - Structure commercial deals
 - Confidentiality agreements
 - License agreements
 - Startup companies
 - Industry sponsored research agreements
 - Collaboration agreements
- Research support
 - Material transfer agreements (MTAs)



Innovation & Digital Health Accelerator (IDHA)

- Identify, catalyze and support new opportunities for innovation
- Promote and facilitate grassroots innovation

Translational Research Program (TRP)

- Stimulate the development of non-clinical and human clinical trials

Translational Neuroscience Center (TNC)

- Innovative clinical programs; outstanding basic science; and efficient translation of novel ideas into practical tools for diagnosis, treatment and prevention of childhood diseases

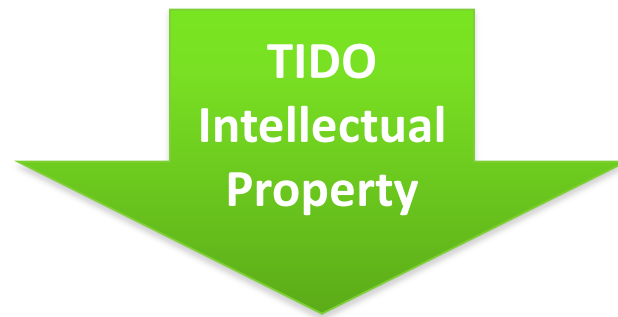


Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

TIDO mediates agreements
around intellectual
property with commercial
partners



Academic Medical Center

- **Clinical care**
- **Basic research**
- **Translational research**
- **Clinical research**
- **Publication**
- **Training**
- **Dissemination of knowledge**

Commercial Partner

- **Product development**
- **Scale up and testing**
- **Regulatory approval**
- **Manufacturing**
- **Marketing**
- **Sales**



Boston Children's Hospital
Until every child is well™



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

History of Ownership of Intellectual Property

- Most research at Boston Children's is federally funded
- Prior to 1980, federal funding agencies owned patents
 - Makes sense, they paid for it
- Very little economic benefit from patented discoveries
 - Only 4% of federally funded research was licensed



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

The Bayh-Dole Act P.L. 96-517 (1980) 35 U.S.C. § 200

- Grants universities/AMCs the right to elect title to patents arising from federally funded research
- Rationale: to promote transfer of taxpayer funded research from lab bench to the marketplace for public benefit
 - Create jobs
 - Create companies and industries
 - New products for public benefit
- Provides incentives to institutions, inventors and companies to participate



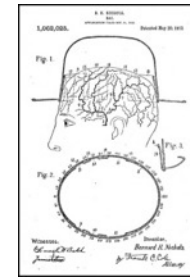
Boston Children's IP Policy

- Updated policy in 2015:
 - Addresses the increasingly complex environment
 - Addresses issues such as collaborations with industry, startup companies, distribution of copyright and consulting
- This IP Policy is designed to support our mission of translating the excellence of laboratory and clinical research and clinical care into lifesaving biomedical products, devices, software and procedures for the public benefit.
- Through active partnering with biotechnology, pharmaceutical, IT and medical device companies at all stages, Boston Children's can better translate our world-class, cutting-edge research, discoveries and innovations into products that benefit the public.



What is Intellectual Property?

- Set of laws covering ideas and discoveries, and other intangible property, including
 - Inventions
 - Patents
 - Copyright
 - Trademark
 - Materials



Boston Children's Hospital
Until every child is well™



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Who owns my Intellectual Property?

Boston Children's ownership of IP is tied to the resources used to develop it.

Boston Children's owns IP when any of the following apply:

- The IP was developed in whole or in part using Boston Children's facilities; or
- The IP was developed in whole or in part using materials, funds or other resources owned or administered by Boston Children's; or
- The IP is related to the inventor/author's responsibilities at Boston Children's



Boston Children's Hospital
Until every child is well™



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Joint Appointments & Participation Agreement

- The IP Policy applies to all Boston Children's faculty, including faculty with joint appointments at other institutions
- Boston Children's will respect faculty obligations to other institutions
- On the Participation Agreement, list other obligations and TIDO will work with those institutions to determine how to fairly share the rights to any IP generated by a faculty member
- The relevant section of the Participation Agreement is Paragraph 5, which includes the following language: "I further agree to assign and do hereby assign to CHILDREN'S all Intellectual Property developed by me as a Covered Person, subject to any existing obligations that I have identified on Exhibit A..."



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

Copyright

- Creative work fixed in a tangible medium, such as:
 - Journal articles, scholarly work and books
 - Photographs and drawings
 - Software
- Academics Works:
 - a subset of copyright related to your academic appointment and shared for public benefit



Who owns a copyright? May I transfer a copyright?

- Copyrights are owned by Boston Children's, but
 - You may transfer any academic copyright, without Boston Children's permission, for academic or charitable purposes
 - You may receive royalties and honorarium for academic works
 - You own private works of authorship (such as textbooks and novels) that are not made with Boston Children's resources



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

Disclosure of Inventions

- Examples of inventions:
 - Composition of matter
 - Design
 - Device
 - Manufacture; or
 - Method
- Inventions must be disclosed to TIDO
- Our office will work with you on patenting and licensing
- **To protect inventions, disclose to TIDO before discussing publically or publication**



Startup Companies

- Startup companies are an important way to commercialize discoveries
- Before starting any company or receiving equity from a company taking a license to Boston Children's IP, you must contact your Chief or Program Director, TIDO and the General Counsel for approval
- TIDO negotiates the agreements with the startup companies



Boston Children's Hospital
Until every child is well™



**HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL**

Consulting Agreements

- Faculty may consult for up to 20% of your professional time, providing that your Chief, Program Director or VP approves
- Consulting agreements require review by the General Counsel's Office, and the inclusion of Boston Children's mandatory consulting terms
- Exclusions from these requirements:
 - Speaking engagements for *de minimus* or no compensation
 - Expert witness testimony do not require prior approval or review



Conflict of Interest

- The Conflict of Interest Committee reviews situations in which involvement with a company could be seen to influence the impartiality of your research, such as:
 - Holding equity in a company that is commercializing your research
 - Being on the Scientific Advisory Board of a company sponsoring a clinical trial
- In such situations, the conflicts committee sets up a management plan to provide oversight if there is a conflict
- Before accepting equity in a startup, you should meet with the conflicts committee



Foundation or Department/Program Investments in Technology

- If BCH and/or the Department or Program make an extraordinary investment (over \$100,000) to further your research, they will be repaid through royalties, if any, and this will affect the inventors' royalty share
- A meeting will be held with you, your Chief/Department Head, TIDO and the General Counsel's Office to discuss the investment and how it will affect royalty distribution



Boston Children's Hospital
Until every child is well™



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Transferring Materials:

mta@childrens.harvard.edu

- TIDO will provide and negotiate Material Transfer Agreements (MTA)
- A new self-service MTA is available for materials that fit the following criteria:
 - Chemical and biological materials
 - Transfer is to a non-profit
 - Not human tissue
 - Does not have third party obligations
- Transfer of materials to or from commercial entities:
 - A full MTA required and TIDO will negotiate
- Human tissue or samples, or materials that raise safety concerns
 - A full MTA required and TIDO will negotiate



Revenue Sharing from Licensing of Intellectual Property

Party	Royalty Share
Inventor(s)	30%
Research Endeavor (e.g., lab)	12.5%
Department or Program	12.5%
Boston Children's	30%
TIDO	15%



Questions?

The Technology and Innovation Development Office (TIDO) administers the IP Policy and is here to support you in your vital research and innovation work.

Contact:

[Your department's licensing manager](#)

or

TIDO@childrens.harvard.edu

617-919-3019

Guidance Documents:

www.childrensinnovations.org



Boston Children's Hospital
Until every child is well™



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL