

Frequently Asked Questions
about the
Intellectual Property Policy
For Partners-Affiliated Hospitals And Institutions

The Role of Intellectual Property at Partners-Affiliated Hospitals and Institutions

Researchers, clinicians, faculty and others at Brigham and Women’s Hospital, Massachusetts General Hospital, McLean Hospital and Spaulding Rehabilitation Hospital, and their affiliated institutions, may make inventions, create written materials, software, or tangible materials (such as biological molecules), or create other “intellectual property” that has the potential to further the institutions’ charitable missions by improving medical care and contributing to medical research or education. (For convenience sake, BWH, MGH, McLean and Spaulding, and other affiliated hospitals are referred to as “the Hospitals” and, collectively with their other affiliated institutions, are referred to as “the Institutions.”) In many cases, this potential value can be fully realized only by taking certain steps to protect the intellectual property, and then executing a license or other arrangement with a company to develop the intellectual property into a product. Patent and copyright protection, in particular, can provide the incentive for a company to invest the resources necessary to develop the technology into useful products. Licensing of intellectual property is not only important for the translation of inventions and copyrightable works into products but also establishes relationships with companies that can lead to them sponsoring research at the Hospitals. Finally, translation of inventions and copyrightable works made at the Institutions into successful products may also generate income, usually in the form of royalties, which are paid to the Institutions and shared with the creators of the intellectual property.

The purpose of the *Intellectual Property Policy for Partners-Affiliated Hospitals and Institutions* (the “Intellectual Property Policy” or sometimes just the “Policy”) is to outline how intellectual property created at the Institutions is owned and managed and how income derived from this activity is distributed. This document summarizes the key terms of the Policy in a question and answer format. It is not intended to summarize the entire Policy or to alter the Policy in any way. It should be read in conjunction with the Policy itself which provides the complete treatment of each subject. For more information or to obtain a copy of the Policy, contact the office of Corporate Sponsored Research and Licensing.

Who administers the Policy?

The Policy is administered by the office of Corporate Sponsored Research and Licensing (“CSRL”) which has separate offices at BWH and MGH. Staff members of Brigham and Women’s Hospital should address questions to the Director, CSRL, BWH while staff members at Massachusetts General Hospital, Spaulding Rehabilitation Hospital and

McLean Hospital should address questions to the Director, CSRL, MGH. Faculty at the MGH Institute of Health Professions should first direct their questions to the Academic Dean.

Who is covered by the Policy?

The Policy applies to all Medical or Professional Staff (including individuals holding appointments as Visiting Staff) of MGH, BWH, McLean and Spaulding or a hospital affiliated with any of them; and to each faculty member, student, and employee of the Hospitals or another Institution (whether their activities at the Institution are full- or part-time), including employees of the Hospital-affiliated physicians' organizations and foundations. The Policy also applies to each visitor from, student or researcher of, or other person primarily affiliated with any other institution, and each person holding a fellowship, who performs educational, research, clinical or other activities at an Institution. People covered by the Policy are referred to as "Members."

What is the "Intellectual Property Acknowledgement?"

The Institutions have long required that Members sign a document that acknowledges their obligations under the Intellectual Property Policy. For many years this document has been called "the Participation Agreement;" it has recently been changed and is now called "the Intellectual Property Acknowledgement." It is important to note that a Member is subject to the Intellectual Property Policy regardless of whether s/he signs the Intellectual Property Acknowledgement.

What types of "Intellectual Property" are covered by the Policy?

The bulk of this Policy is devoted to the two types of intangible, or "intellectual," property most common in an academic institution. The first type is inventions. These are frequently protectable by obtaining a patent; *however the Policy covers many inventions and discoveries even if they are not patentable.* The second common type of Intellectual Property consists of written works and other materials that are protectable as copyrighted works. (Software is always copyrightable and in many instances may also be patentable; the Policy treats any software that is patentable as an invention.) Although less significant at the Institutions, the Policy also addresses two other common types of intellectual property: trademarks and trade secrets. Finally, the Policy also addresses tangible research property, which are research results in a tangible form such as biological molecules.

What is an invention? What inventions are patentable?

For the purposes of the Policy, an "Invention" is defined as any patentable invention (as defined by patent law), or any other idea or its embodiment that is potentially patentable or, even if not patentable, may have charitable or commercial value. Generally Inventions consist of potentially new and useful processes, methods, machines, compositions of matter or articles of manufacture or any improvement of any of these, whether patentable or not.

A patentable Invention is made through a two-step process, consisting first of the conception of an idea and second the written description of the idea or the conversion of the idea into a model, prototype or process (also known as “reduction to practice”). To be patentable the Invention must furthermore meet other specific legal criteria: it must be “new” (that is, it has not been previously used or known to the public), “useful,” and “non-obvious” to a person of average skill in the field of the Invention. (Section 4.0 of the Policy.) A patent provides a valuable commercial advantage because it provides a period of twenty years (after the date of filing of the patent application) during which the patent owner (or a company which has licensed the patent) can exclude others from making, using, selling, or otherwise practicing the licensed Invention. In other words, it grants the company a period of “exclusivity” in which to develop, market and sell a product.

However, as described above, for the purpose of the Policy an “Invention” is defined more broadly than just patentable Inventions, and includes a range of ideas that may potentially be patentable or, even if not patentable, may have charitable or commercial value.

What is copyright?

Copyright protects “original works of authorship” such as manuscripts, books, slides, videotapes, disks and many aspects of computer software. Copyright happens automatically once a work is written down, typed or encoded on a computer, or otherwise put into a tangible form or medium. Because copyright does not protect ideas themselves, it does not prevent other people from using the ideas contained in copyrighted works, but it does prevent them, among other things, from copying the way the ideas are expressed, or copying or distributing the work (Section 7.0 of the Policy). However, if the ideas contained in a “Copyrighted Work” (as described in the Policy) amount to an Invention or discovery, they may also be protectable by patent.

If I think I have made an Invention or Copyrightable Work, what should I do?

In almost all cases, with the notable exception of Academic Works, you should disclose to CSRL Inventions or Copyrightable Works that you make while you are a Member of an Institution. For more detail as to what must be disclosed and when, please refer to Sections 6.0 and 11.0 of the Policy.

All disclosures should be made to CSRL using an Invention Disclosure Form or a Copyright Disclosure Form, respectively (at McLean, Invention Disclosures should be made to the Vice President, Research Administration). The Disclosure Forms should be filled out as completely as possible in order for CSRL to evaluate the commercial potential of the Invention or Work and to determine whether the Institution has an ownership interest.

Who owns Inventions and Copyrightable Works?

During the period of time that you are a Member, the Institution owns all Inventions and Copyrightable Works (other than Academic Works—see Section 8.1.4 of the Policy) which you conceive or reduce to practice, author or create:

- in performing activities that received direct or indirect financial support from the Institutions;
- in performing activities that made substantial use of any space, facilities materials or other resources of the Institution;
- in performing activities that were otherwise subject to a grant, contract or other arrangement between an Institution and a third party; or
- (in the case of Inventions and Software only) that arise out of or relate to your clinical, research, educational or other activities at the Institution.

The Institution also owns all Copyrightable Works created by you at the request of the Institution, or as part of an Institutional undertaking and, if you are *not* a Professional or Medical Staff or faculty member, any other Copyrightable Work created in the scope of your employment or affiliation with the Institution.

Note that if an Invention or Copyrightable Work meets none of the criteria above, it is owned by the Member. A concept for a new business opportunity, for example, is not owned by the Institution if the concept is unrelated to any activities of the Member at the Institution, a situation most likely to occur with Professional or Medical Staff Members who do not have any administrative responsibilities at the Institution. For additional details regarding ownership of intellectual property, please refer to Sections 5.0 and 8.0 of the Policy.

What about journal articles and other academic publications?

Academic publications of Medical or Professional Staff and students fall under the definition of Academic Works (Section 8.1.4 of the Policy) and generally belong to their authors, in full accord with academic tradition.

Should I publish or let the Hospital file for patent protection?

Both. It is not a matter of having to choose between patents and publications; both are compatible. You should keep in mind that one of the criteria for patentability is novelty – that the idea not be known publicly – and this criteria is lost once there is a publication. Therefore, if you are planning an imminent publication or presentation, contact CSRL to disclose your Invention as soon as possible. CSRL will work with you to protect your Invention as broadly as possible with no or minimal impact on your publication/presentation plans. Once a patent is filed, you are then able to publish or otherwise publicly disclose your Invention without jeopardizing your patent rights.

Are there any other constraints on when I may publish?

If an Invention arose under a sponsored research agreement, some additional delay in publication may be required to comply with contractual obligations.

What happens to Inventions owned by the Institutions?

Once an Invention is fully disclosed, the Director of CSRL will assign a case manager to verify that the Institution owns the Invention. CSRL will determine whether to file a patent application, taking into account the Invention's commercial potential, requirements of any agreement, other pertinent facts. If a decision is made to file an application, the case manager will work with you and outside patent counsel to prepare and file the application, at the Institution's expense. The case manager will explore the commercial prospects, and (for Inventions which are not already subject to licensing obligations) consider potential licensee companies and, when appropriate, negotiate and draft a license agreement to transfer certain commercial rights to the company. If the Inventions is licensed, the case manager will continue to monitor the relationship with the licensee company to ensure diligent development of the licensed Invention. See also Policy Sections 6.4 and 11.4.

Are there other things I should keep in mind regarding copyright?

While "Academic Works" are owned by Members, other written materials, along with software and video products that are increasingly being developed with Institutional involvement, are often owned by the Institutions under the Policy. It is best that anyone who develops software, videos, patient handbooks, educational materials, or other copyrightable works in connection with Institutional activities be aware of copyright concerns before a project begins, to be sure that the work can be used as intended when it is finished. This is particularly important if consultants or others outside the Institution are involved, if the work is based on pre-existing material, or if you plan to distribute it outside the Institution. See Policy Sections 8.3, 9.0 and 10.0.

What are my obligations with respect to Tangible Research Property?

Tangible Research Property (or TRP) that is patentable is treated as an Invention while any TRP that is copyrightable is treated as a Copyrightable Work. TRP that is neither patentable nor copyrightable should be disclosed if the originator intends to distribute the TRP outside the Institutions. The Institutions recognize that making TRP available to others, particularly academic colleagues, is an important part of their research mission. However, because of safety issues, patient consent issues, contractual obligations, as well as policies, laws and regulations relating to distribution of certain categories of TRP, distribution of TRP to industrial entities, distribution of TRP comprising patient tissues, and distribution of certain categories of TRP to any outside entity must first be approved by CSRL. See Policy Section 16.

May I sign “material transfer agreements,” confidentiality agreements, or other agreements that address intellectual property without institutional review?

No. While you are a Member, all such agreements must be reviewed and approved by the Institution and, in most cases, the appropriate office to review the agreement will be CSRL. See Policy Section 4.

If I consult for a company, can the company own my Inventions?

Companies usually expect to own inventions made in the scope of a consultancy, even though such inventions would, in many cases, be considered “related Inventions” (see Section 5.2.2 of the Policy) which are normally owned by the Institution. If you wish to consult, the Policy provides a way to obtain an exception from Institutional ownership – in advance – for Inventions that relate to your work at the Institution but which are created off-site and at the expense of the company. In order to obtain that exception, you must submit your consulting agreement to CSRL for review (Section 5.2.2.1) which review is in any case required under the Institution’s Consulting Policy (<http://healthcare.partners.org/OGCpolicies/Consulting.pdf>).

How are royalties distributed?

All royalties are collected by CSRL and are distributed at regular intervals throughout the fiscal year. In general, royalties on Inventions, Copyrightable Works, and Tangible Research Property, net of certain expenses attributable to protecting and licensing the property, are distributed as follows: 25% to the Creators, 25% to the Creators’ Laboratory or Unit, 25% to the Creators’ Department or Service and 25% to the Creators’ Institution. (“Creators” means either the inventors of an Invention, or the individuals who contributed to a copyrighted work and who are entitled to a share of royalty income under Section 17.3 of the Policy. If there is no clear Lab or Unit, that share will be paid to institutional accounts in the name of senior Creators, the funds to be used to support their research or other charitable activities while they remain at the Institution.) However, income from Copyrightable Works that are “made for hire” such as computer programs written by employees hired to be programmers is generally retained by the Institution. Laboratories may adopt their own policies for reallocating the Creator’s share of income from Copyrightable Works – for example, devoting it to lab purposes or sharing it with all lab members, if the work to be created is a team effort. (Section 17 and Table I provide full details on income distribution.)

What happens to my share of royalties if I leave the Institution?

If you leave the Institution, your portion of the Creators’ share will continue to be paid to you. The rest of the proceeds will remain at the Institution.

What happens if I don’t agree with a decision made by CSRL?

The Professional and Institutional Conduct Committee of Partners HealthCare, which includes representative members of the Hospital communities, provides general oversight of the administration of the Policy. Disputes shall be resolved under the oversight of this Committee. (See Policy Section F.)

Are there other policies that I should know about?

You should be aware that you may be subject to a number of other policies. In particular, two important policies address conflicts of interest: the “Partners HealthCare System Code of Conduct”(<http://healthcare.partners.org/OGCpolicies/Code/index.html>), and the “Harvard Medical School Policy on Conflicts of Interest and Commitment” (<http://www.hms.harvard.edu/integrity/conf.html>).

In addition to the Consulting Policy mentioned above (<http://healthcare.partners.org/OGCpolicies/Consulting.pdf>), other relevant policies and guidelines include “Guidelines Regarding Gifts from Industry to Support Educational Programs” (<http://intranet.partners.org/OGC/policies/EducationalGiftPolicy.pdf>); “Guidelines for Attribution of Credit and Disposition of Research Products” (<http://www.hms.harvard.edu/fa/attribution.html>); and the HMS “Faculty Policy on Integrity in Science” (<http://www.hms.harvard.edu/integrity>), which includes the above-referenced conflicts of interest policy.

Additional policies and guidelines are distributed from time to time by Harvard Medical School and Partners HealthCare System and the individual hospitals, some of which are posted on <http://www.hms.harvard.edu/fa/> and <http://intranet.partners.org/ogc/OGCpolicies.asp>.