

HARVARD UNIVERSITY OFFICE OF TECHNOLOGY DEVELOPMENT

INVENTOR'S HANDBOOK

A FACULTY GUIDE TO INTELLECTUAL PROPERTY AND TECHNOLOGY DEVELOPMENT



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Research, discovery, and the rewards of invention — your role in technology transfer at Harvard.

The Office of Technology Development serves the faculty by partnering with them to develop and implement innovative strategies to protect and commercialize their new inventions and discoveries.

This guide is your starting point in bringing your invention to OTD and the world at large.

Report

Protect

Market

Monitor

Partner

"Harvard's faculty is at the forefront of diverse fields of intellectual endeavor, generating new ideas and technologies with the potential to solve many important problems. A major goal of the University is to enhance the translation of our faculty's research into useful new products that can benefit society. The Office of Technology Development partners with Harvard faculty to help develop their inventions and launch them successfully in the world. Working with OTD assures the faculty that promising discoveries made in their labs reach their potential through licensing and research collaborations with industry."

Steven E. Hyman, M.D., Provost

To the Faculty:

Harvard's position among the world's great research universities is matched by its commitment to ensure that new inventions and discoveries made by our faculty are developed for the public good. The Office of Technology Development stands ready to help Harvard faculty advance their new technologies to the fullest so that they can save lives, heal the sick, conserve resources, spur economic development and achieve other vitally important aims. In so doing, we are vigilant in protecting the interests of the Harvard faculty, enabling them to carry out their research in the open and independent tradition of the academy.

We support faculty at all points in the process of technology development and transfer to industry for commercialization. You may need assistance to generate sponsored research funding and partnering with industry; you may have made a discovery that appears to be patentable; you may be interested in forming a start-up company; or you may simply want a sounding board regarding your latest research results and their potential for commercialization. Our team brings together scientific knowledge, business acumen and longstanding experience to give you the right service at the right time. Moreover, through the Technology Development Accelerator Fund, we may even be able provide early-stage funding in order to advance projects to a proof-ofconcept threshold.

Our success is due in large part to the dedication of Harvard's outstanding faculty, who regularly welcome us into their labs and share their findings. It is never too early to call on us, because even a nascent discovery requires planning and protection if it is to ultimately flourish. We look forward to hearing from you and working with you to protect and develop the fruits of your research.

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Isaac T. Kohlberg / Senior Associate Provost and Chief Technology Development Officer

ADVANCING YOUR DISCOVERIES

The Office of Technology Development has one fundamental purpose — to advance the development of the Harvard faculty's groundbreaking discoveries for the good of society.

Research at Harvard often yields discoveries that add immensely to knowledge and bring great personal satisfaction to faculty members. But your research may also have implications for broader applications that serve the public good through the process of technology transfer. The Office of Technology Development provides you with an easily accessible source of expertise and experience to protect your invention and develop strategic collaborations with industry through licensing, sponsored research and new venture agreements.

The collaborations may enhance intellectual exchange, foster the widest possible recognition for your efforts and attract financial sponsorship of your research. Harvard typically receives license fees or royalty payments in return for the transfer of commercial rights to inventions that stem from faculty research. The University shares this income with you, both personally and as funding for your laboratory and department.

Technology transfer can be a streamlined process because OTD puts its staff of professionals with broad experience in science, business development, intellectual property and contract law to work for you. After you notify us of your invention, we provide expert assistance in protecting and marketing it, in developing relationships with industry to identify and contract with the best possible commercial partner and in monitoring and enforcing the partnership agreement.

Using the services of OTD assures you of an efficient, independent path to technology transfer. We strive to use your time judiciously so that you can concentrate on your research. We structure agreements so that your discoveries are appropriately protected while you maintain the right to conduct your work and publish results without interference, in accordance with the time-honored values of the academy.

Harvard's Intellectual Property Policy

To review the Concise Guide to Harvard's Intellectual Property Policy: www.otd.harvard.edu/resources/ guidelines/ippolicy

To read the full policy: www.otd.harvard.edu/resources/ policies/IP



What is intellectual property?

Intrinsic to the work of a university, intellectual property refers to ideas, processes or inventions that are the products of intellectual endeavor. This often intangible form of property can be protected from unauthorized use, and it can be bought, sold or licensed.

Whose property is it?

Under Harvard's policy, the University owns intellectual property that is generated through research conducted with the use of its facilities and resources. All royalties and most fees resulting from the intellectual property are shared on an approximately 50/50 basis between Harvard and the individuals involved in its discovery. The inventors' portion includes an allocation for support of their research. The University uses its share to support additional research and academic programs.



REPORTING YOUR INVENTION

The first step on the critical path to the commercialization of your invention is to inform OTD so that we can help you make certain that it is properly protected.

Reporting of any potential inventions made during research at Harvard is integral to academic discovery. Most scientific research at the University receives funding from either federal or private sponsors who require such reporting.

When you report your invention to us, we evaluate it for patentability and advise you on how to avoid premature disclosure to third parties, which may jeopardize its potential commercial value. Disclosure is construed very broadly under patent law, extending to informal discussions with Harvard or outside colleagues and unprotected emails as well as public presentations and publications. Further, patent rights are dependent on publication dates. OTD recognizes that publishing and scientific discussion are of paramount importance, and when addressed at an early stage, these activities can remain both protected and unhindered.

The reporting procedure is accomplished through a simple Report of Invention Form that calls for a basic description of the invention and its intended commercial application, the people who contributed, other organizations that may have been involved and sources of funding and support.

Why is reporting important?

Reporting your invention is vital to the protection of a valuable intellectual asset. With proper safeguarding, your invention can be developed to its fullest capacity. If this step is not taken, it is unlikely that the invention will be funded and commercialized so that it can provide its maximum benefit to society.

Reporting An Invention

The Office of Technology Development has created a secure and easy-to-use online submittal form for reporting inventions. The form can be accessed through the following link: http://www.otd.harvard.edu/inventions/inventors/roi

Technology Transfer at Harvard University



What is an invention?

Harvard's intellectual property policy defines inventions as ideas, discoveries and/or know-how that are either patentable or potentially patentable. In general, an invention is a new and useful method, composition (such as a cell or chemical compound) or apparatus possessing unique properties and offering real advantages to users. Any associated or supporting technology is considered to be part of an invention.

Harvard faculty generate other types of intellectual property in addition to inventions, such as content-based scholarly works and unpatented materials. For more about these forms of intellectual property, please refer to the Concise Guide to Harvard's Intellectual Property Policy: http://otd.harvard.edu/resources/guidelines/ippolicy

Who is an inventor?

An inventor is someone whose ideas and experimentation are responsible for the conception of an invention, or who has made a substantial intellectual contribution to the conception of an invention. Inventorship is a legal determination. An invention may have multiple inventors. In a university setting such as Harvard, inventors may include the faculty member in whose laboratory the intellectual property originated, students who carried out work in the lab and authors of papers concerning the invention.



PROTECTING YOUR INVENTION

An invention must be protected if it is to be commercialized in the best possible manner to benefit society, the inventor and the University. A patent is the surest means to protect an invention.

A U.S. patent prevents others from making, using or selling an inventor's intellectual property for 20 years from the date of filing, with varying periods of protection in foreign jurisdictions. This period of exclusivity is an important incentive for commercialization because it provides time for the necessary investments in development and marketing to be recouped. Licensing of patent rights to commercial partners can lead to collaborations that drive important projects forward.

OTD provides you with advice on the patentability of an invention. To be patentable, a discovery must meet three basic criteria.

It must be useful. The invention needs to serve a practical purpose, a criterion that most serious inventions meet without challenge.

It must be novel. An invention can be considered novel if it differs demonstrably from ideas or physical materials that have been known, used, published or patented.

A novel invention may include known features, and a new use for existing processes or products may meet the standard for novelty. The novelty of an invention can be adversely affected by premature disclosure, or from undue delay of its disclosure.

It must not be obvious. A patentable invention may not be obvious to a person of ordinary skill in the same field of research. As the determination of "obvious" and "ordinary skill" are open to interpretation, this criterion may be subject to disagreement.

If the invention is determined to meet the criteria for patentability, OTD files a patent application with the U.S. Patent and Trademark Office, which publishes patent applications 18 months after initial filing. If the invention requires further development and validation before a patent is filed, OTD shepherds the process and provides specific advice at critical points.



Road Map for Typical U.S. Patent Prosecution

What is a patent?

A patent is a commercial tool to protect an invention by giving the patent owner up to a 20-year limited monopoly over the technology. At Harvard, an invention is defined as an idea, discovery or know-how that is patentable or potentially patentable, together with its associated or supporting technology.

What is patentable?

Patentable inventions include processes, machines, compounds, compositions of matter and methods of manufacture, together with novel improvements to existing inventions of these types.

What does a patent application contain?

A patent application is a portfolio of information about the invention. It contains an abstract; a discussion about the state of the art in the field of the invention; and a detailed description of the invention, including specific claims and, typically, examples and graphics. A sworn statement by the inventor completes the application.



MARKETING YOUR INVENTION

Bringing an invention to the marketplace requires expertise, resources and effective business networks. OTD works with faculty to determine whether it is more appropriate to partner with an existing company or to create a start-up venture. Each of these approaches has its unique advantages and challenges.

No matter which path is ultimately chosen, OTD provides expert guidance and assistance throughout the process. We professionally "package" your invention, target it to the market, design the value proposition for the technology and prepare an opportunity prospectus for potential partners and/or investors, whom we identify with your input, leveraging our extensive network of contacts in the business and venture community. We then proceed to hold preliminary discussions and analyze the best path forward. As such discussions progress and a greater level of interest is expressed by a potential partner, we organize in-depth meetings at which additional

information is provided under confidentiality, frequently including scientific presentations by the inventor, as appropriate.

We encourage you, the inventor, to cultivate your own relationships with industry and explore potential mutual interests with any colleagues you may have in industry. OTD stands ready to coach you, as you see fit, in such interactions, and provide you with advice and counsel, as appropriate. It is important that you let us know sooner rather than later when you have initiated a discussion with industry.

How does OTD identify potential partners?

After reviewing potential applications with the faculty inventor and evaluating partnership possibilities, OTD develops a licensing strategy based on the technical and marketing challenges presented by the invention. We actively identify likely candidates for a commercial partnership through a variety of methods, including the mobilization of our extensive contacts in industry. With the inventor's assistance, we craft a non-confidential marketing summary and approach potential industrial partners directly.

COLLABORATIONS WITH INDUSTRY

The next step in making the invention available to the public is to develop technology transfer agreements with an industrial partner that OTD determines to be well-equipped and well-positioned to commercialize the technology. Based on the nature of the technology and other factors that we analyze, the best partner may be either an existing company or a start-up.

best way to commercialize an invention by

analyzing a variety of factors including:

to provide a platform for multiple

Limited interest of existing companies

• Availability of venture capital, together

with the interest and track record of

• Level of commitment of the inventor(s)

to the commercialization process.

"champion" for both the technology

The presence of a true business

• The management team of the

and the new venture.

proposed start-up.

• The potential of the technology

market/product opportunities.

• The competitive environment.

in licensing the technology.

likely investors.

Licensing

In structuring partnership agreements with licensees, OTD negotiates terms that benefit all the parties concerned — the inventor, the University, the partner and the public. We also negotiate the key elements of a license agreement, including provisions governing the scope of the license (whether exclusive or non-exclusive rights will be granted), the breadth of the field, reporting and diligence obligations of the licensee to Harvard, and royalty considerations payable to Harvard to ensure that fair value will be received based on future sales of any licensed products.

Start-up companies

Only certain inventions may justify the formation of a start-up company. OTD can help to determine whether this path is the

What is a license?

A license is a tool by which the owner of intellectual property grants another party permission to assume some or all of the owner's rights to the property, whether or not it has been patented. Licenses typically take the form of written agreements that describe each party's rights and responsibilities under the agreement; they may or may not be exclusive or restricted. In negotiating licenses, OTD always retains the right to use an invention for noncommercial purposes at Harvard and elsewhere.

Start-Up Company Formation

Desirable When

There is a Dominant Intellectual Property Position

There is an Early Stage High Risk Technology There are Multiple Applications of the Technology (i.e., a "Platform" or "Enabling" Technology) There is no Existing Industry

The Investigator Desires a High Level of Active Participation

Potential Advantages

Greater Focus on and Commitment to the Technology Opportunity to Become an Equity Stakeholder

More Expeditious Development of Core Technology

Potential Disadvantages

Amount of Time Required to Start Company Financial Instability

Difficulty Recruiting Quality Management

Interest Issues (Real and Perceived)

Conflict of

INDUSTRY-SPONSORED RESEARCH

OTD is also responsible for sponsored research in which facultydriven projects are supported by external funding from industry. Industry-sponsored research agreements (ISRAs) are a natural extension of OTD's licensing activities.

With our knowledge of the market, business contacts and ability to cultivate and sustain productive relationships with industry, we can help you to form strong collaborations even when commercialization is still far in the future. Such collaborations include broad-based strategic alliances with industry that may involve the funding of multiple laboratories performing investigator-initiated research around a common theme, offering critical mass, which may complement an avenue of research relevant to the sponsor. We take great care not to limit inventors' rights to publish and present their research results. We understand the cultural ecosystem of both industry and the university, so we are able to craft successful ISRAs that meet the needs of all concerned, protect academic freedom and help advance research and innovation.

University policies in addition to the IP Policy, as well as school-specific policies, may apply to your Harvard activities, including the performance of sponsored research and the management of conflicts of interest and/or commitment, all of which we recommend the faculty familiarize themselves with.



Driving Technology Transfer



TYPES OF AGREEMENTS

A commercial agreement reflects a dynamic relationship that unfolds under evolving technical and market conditions. The agreement is structured to meet the needs of all its parties — the inventor, the University and the industry partner.

With careful planning, skilled management and well-structured agreements, Harvard researchers and industrial partners can collaborate for mutual, sustained benefit. The primary types of agreements negotiated by OTD include:

- Confidentiality Agreements (CDAs) or Non-Disclosure Agreements (NDAs) are used to protect the confidentiality of an invention, technology and prepublication information during evaluation by potential licensees and industry collaborators.
- Industry Sponsored Research Agreements (ISRAs) or Research Collaboration Agreements (RCAs). ISRAs describe the terms under which sponsors provide research support for faculty-initiated research projects. RCAs are similar to ISRAs, but contemplate the sponsor performing a collaborative role in the research. OTD ensures that ISRAs and RCAs protect the right of Harvard investigators to freely conduct their research without interference or outside direction, and that they will be able to freely publish and/or present their research results.
- Inter-Institutional Agreements (IIAs) describe the terms under which two or more universities or other institutions will collaborate to market, license and share in the revenues that may be received from licensing jointly owned intellectual property.
- License Agreements describe the rights and responsibilities related to the use,

development and sales of commercial products covered by intellectual property developed at Harvard. Harvard license agreements stipulate that the licensee must diligently seek to develop the licensed technology into a commercial product for the public good, and provide a fair and reasonable return to the University. License agreements typically include a specific, dedicated development plan that sets forth the steps that the licensee will take to develop and commercialize the licensed technology. A license may be granted to either an established company or a start-up company, also known as a NewCo (for new company). In certain cases, Harvard may negotiate to receive a reasonable equity position in such NewCos.

- Material Transfer Agreements (see next page.)
- Option Agreements, or option provisions within ISRAs, describe the conditions under which an industrial sponsor is granted the right to negotiate a license to intellectual property. Option agreements also may be entered into with a company that wishes to evaluate a specified technology prior to entering into a full license agreement.

While the parties enter into the agreement in a spirit of cooperation, close monitoring is essential, and troubleshooting may be necessary from time to time. OTD makes certain that each party meets its obligations and remains on course.



What are Material Transfer Agreements?

Scientific research often requires the exchange of proprietary physical materials — such as cell lines, pharmaceuticals and chemicals — among researchers. To protect all parties in such an arrangement, OTD negotiates a carefully crafted material transfer agreement (MTA), a contract for governing the incoming or outgoing exchange of tangible research materials between Harvard researchers and other academic, government and commercial organizations. MTAs offer important protections regarding such issues as ownership, the ability to publish and rights to resulting inventions. OTD receives and negotiates close to 1000 MTAs per year through an efficient, web-based process.

For detailed information on material transfer agreements: http://www.otd.harvard.edu/resources/agreements/materialtransfer

BRIDGING THE DEVELOPMENT GAP The Technology Development Accelerator Fund

The primary obstacle to developing university technology and partnering with industry is the gap (sometimes known colloquially as "death valley") that exists between early-stage research results and key proof-of-principle data that is typically required for industry to make a commitment and invest in the technology for further development and commercialization. Harvard has taken the initiative to help close this gap by launching an innovative, dedicated funding vehicle known as the Technology Development Accelerator Fund. In its first three years, 2007 – 2009, the Accelerator Fund provided support for 23 projects from across the University with a total investment of more than \$4 million, and one project was transferred to industry during the first year under a commercial agreement, thus providing early validation of the Accelerator model. The Accelerator is designed to be self-sustaining, and to allocate funds annually in accordance with a competitive RFP process. Faculty proposals are reviewed and selected for funding by an external advisory committee comprised of leaders from industry and the venture community. The committee's expertise, together with the expertise of the Accelerator's Chief Scientific Officer, are available to provide advice and guidance to the recipients of Accelerator funding, as needed.

FOSTERING NEXT GENERATION TECHNOLOGIES, CHANGING LIVES, TRANSFORMING THE FUTURE

Harvard University has a special obligation to help make the world a better place. Scientific investigation and the development of next generation technologies comprise the foundation of all progress that improves life and diminishes human suffering. Harvard is determined to hasten the pace of such progress and make certain that research performed at the University will impact the world in profound ways. OTD is the catalyst enabling the public to access Harvard research by fostering close and productive relationships between our internal and external stakeholders — Harvard faculty and the business and venture community, respectively — in order to ensure the transfer of Harvard-originated technology to the private sector for the betterment of society.

Creativity, perseverance, relationshipbuilding and value creation are the hallmarks of technology transfer. OTD offers its experience and expertise to you, Harvard's faculty, in the areas of intellectual property protection, technology development and management, licensing, sponsored research, new venture formation, and technology commercialization. We stand ready to work with you to protect the fruits of your research and promote its commercial development with a minimum of red tape. These activities enhance the ability of the University to serve the public interest while carrying out its academic mission.

Central to OTD's efforts is our commitment to preserve the values, interests and independence of the Harvard research community. We foster dynamic relationships between our faculty and industry scientists in order to establish research collaborations and ensure that emerging technologies are transferred to industry in the hope they will be transformed into useful new products and services. A by-product of this activity is the generation of revenue that is shared among Harvard's inventors and its affiliated schools and departments. Thus, a portion of such revenues is reinvested in additional research and education at Harvard, helping to establish a solid underpinning for the next generation of research and researchers. None of this would be possible without the efforts and leadership of Harvard's remarkable faculty. We thank you, our faculty, who work with steadfast commitment and passion. It is through your inspiration and determination that discoveries forged on the research bench become new solutions to the most intractable problems in science and society. We look forward to working with you to realize the potential and practical benefits of your inventions. If you have any questions about an invention and its commercial potential, we hope you will seek our advice and assistance.

CONTACT INFORMATION

The process of technology development and transfer begins with you. OTD is ready to serve as a resource to Harvard faculty members at any point in the inception or development of an invention. If you have an idea you would like to discuss, or if you have questions about intellectual property, technology development, sponsored research or the technology transfer process, please do not hesitate to contact us.

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