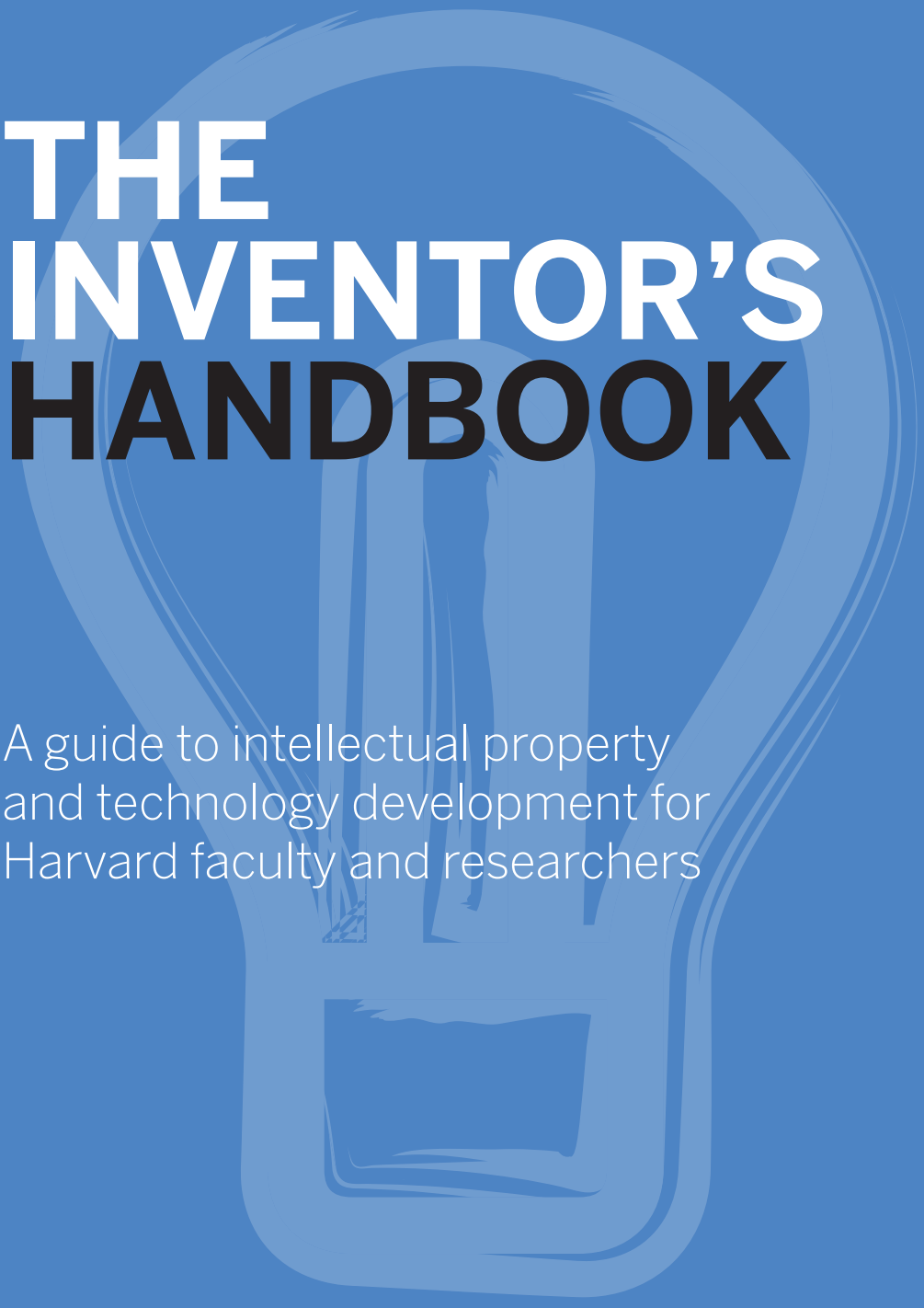
THE INVENTOR'S HANDBOOK



A guide to intellectual property and technology development for Harvard faculty and researchers

HARVARD
Office of Technology Development

Harvard's research enterprise is a wellspring of innovation with the potential to improve lives, transform industries, and create tremendous social and economic value. We're here to help make that happen.

The Office of Technology Development (OTD) promotes the public good by advancing science, fostering innovation, and translating new inventions made at Harvard University into useful products that are available and beneficial to society.

Our integrated, research-focused approach to technology development comprises:

- corporate partnerships and alliances
- intellectual property management
- technology commercialization through venture creation and licensing

We also lead and operate the Blavatnik Biomedical Accelerator and the Physical Sciences & Engineering Accelerator.

Let this handbook be a guide to bringing your innovations to OTD and to the world at large.

The broad overview provided in this publication is not intended to modify or supersede any relevant Harvard policies, which can be accessed online via the Office of the Provost.

6 WHAT IS TECHNOLOGY DEVELOPMENT?

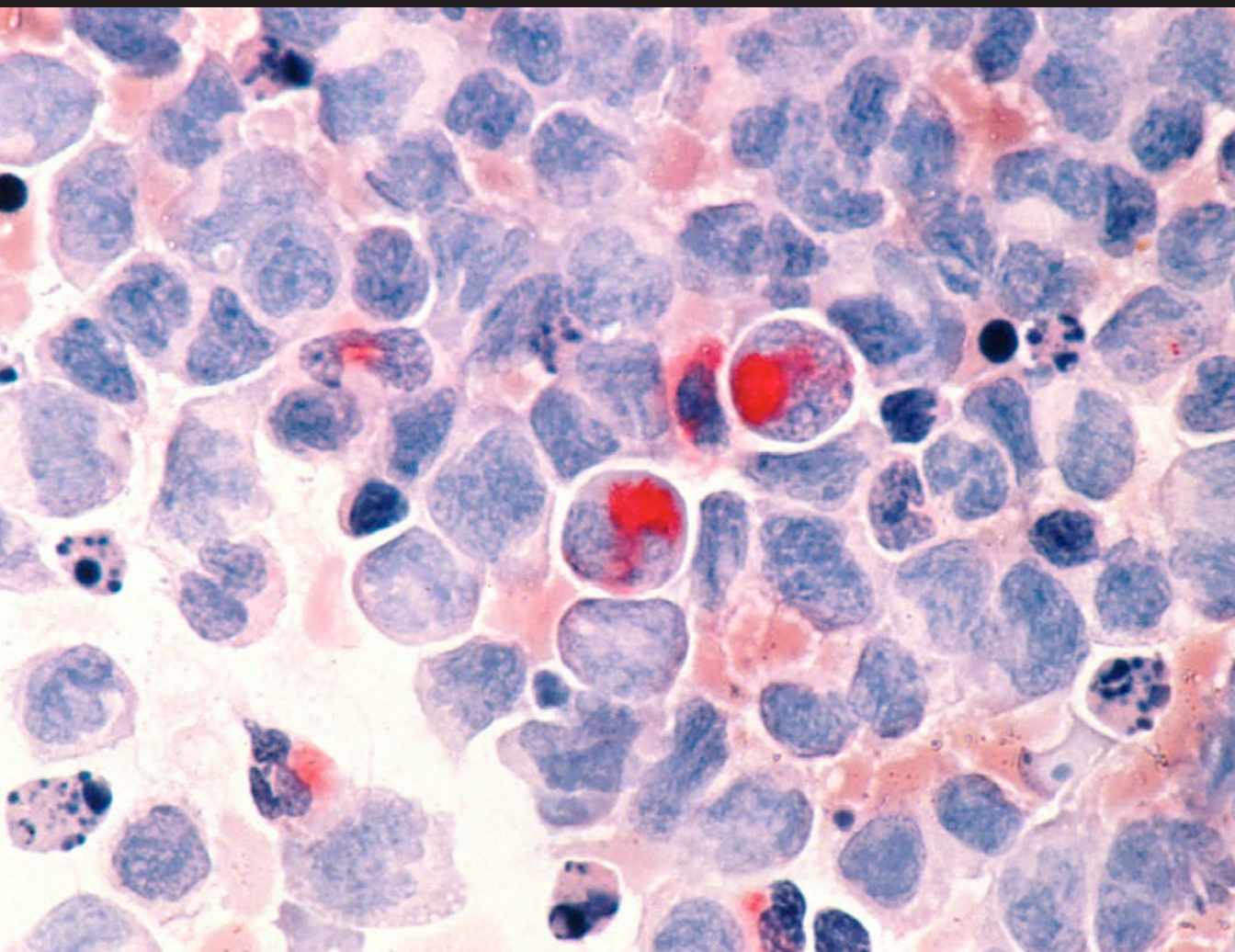
10 ADVANCING YOUR RESEARCH

14 REPORTING AND PROTECTING YOUR INVENTIONS

22 COMMERCIALIZING TECHNOLOGIES

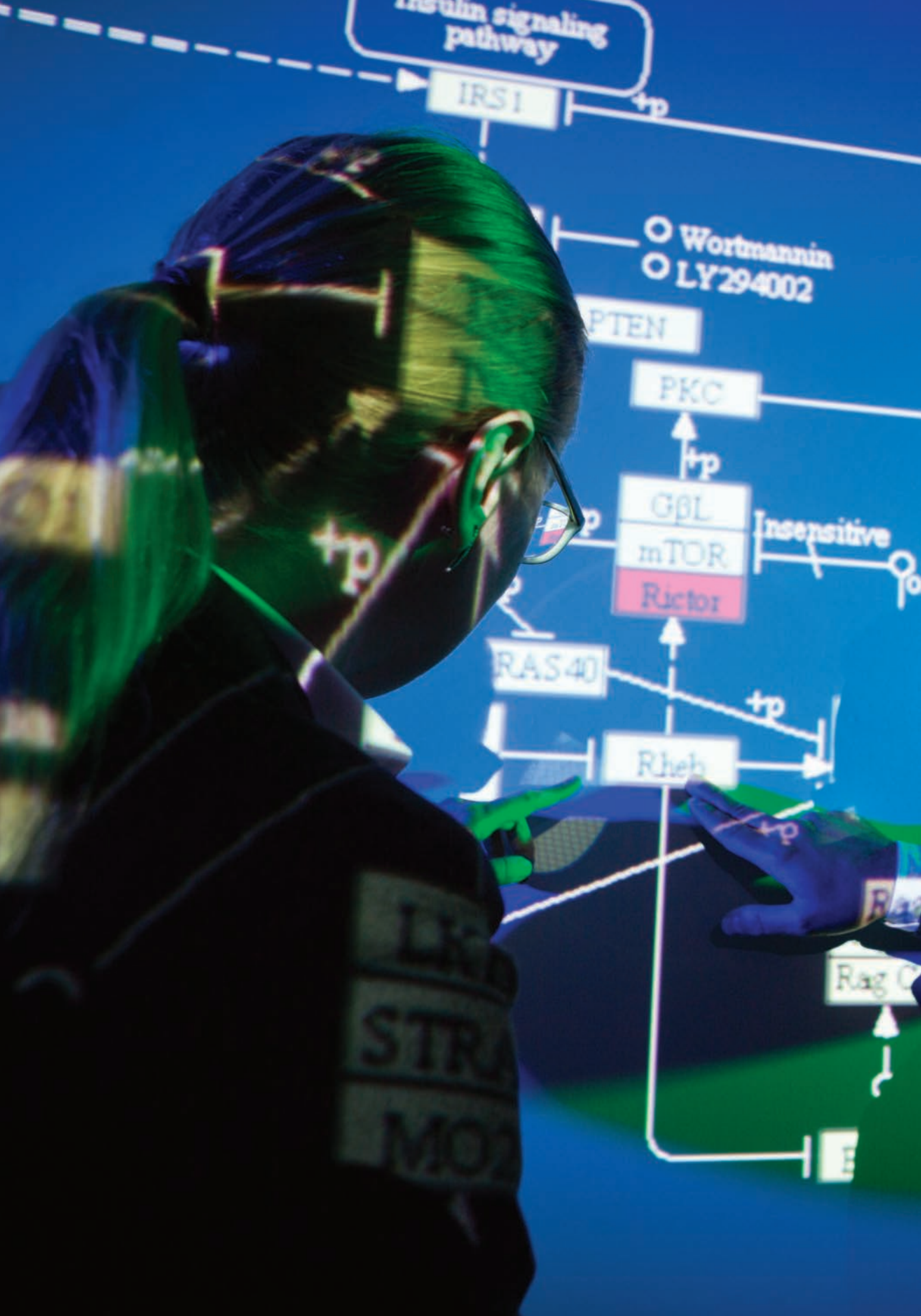
28 TYPES OF AGREEMENTS

30 WHO WE ARE



> Harvard is known as one of the most innovative universities in the world, globally respected for the discoveries that occur in University labs and translate into new products for the benefit of society. Harvard owes that reputation in large part to the ingenuity and passion of its distinguished faculty and researchers, and to its constructive engagement with industry and business. The work of the Office of Technology Development assures faculty that their inventions — whether a new therapy, a better material, or a smart piece of code — will reach their highest potential in the wider world: solving problems and improving lives.

— Provost Alan M. Garber, MD, PhD


Insulin signaling pathway
IRS1
Wortmannin
LY294002
PTEN
PKC
GβL
mTOR
Insensitive
Raptor
RAS40
Rheb

Dear Innovator:

In the course of your research at Harvard, you may develop a technology that has commercial applications. You may seek to obtain corporate funding or to collaborate with industry. You may need support in sustaining the development of a technology that is too far along for federal grants but too early to attract investors. You may be considering forming a startup. Or you may simply want a sounding board regarding your latest discoveries and their potential.

The Office of Technology Development is here to serve your needs. Our team brings together scientific knowledge, business acumen, and a wealth of experience to lend you sound advice and timely service. We take pride in building lasting relationships with Harvard's innovators and with the investors and industry partners that are committed to developing our technologies.

Each one of us in OTD is motivated by your dedication to your work. What drives us is the opportunity to engage with you, understand your research thrusts, and assemble the right partners to skillfully and creatively put your ideas into practical application.

The Inventor's Handbook provides an overview of technology development at Harvard and the ways you can interact with OTD. We hope it will inspire you to work with us.

We look forward to hearing from you.

Isaac T. Kohlberg
Senior Associate Provost
Chief Technology Development Officer


WHAT IS
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The Office of Technology Development has one fundamental purpose — to advance Harvard researchers' groundbreaking discoveries for the good of society.

Research at Harvard often yields discoveries that add immensely to knowledge and bring great personal satisfaction. But your research also may have implications for broader applications that serve the public good. OTD provides you with a ready source of expertise and experience to advance your research through corporate partnerships and accelerator programs; protect and manage intellectual property created through your Harvard research; and develop a commercialization strategy that results in licensing or a new venture.

Collaborations with industry partners may enhance intellectual exchange, foster broad recognition for your efforts, and attract financial sponsorship for your research. In addition, the license fees or royalty payments typically received by Harvard in return for the transfer of commercial rights to inventions are shared with you, the inventor, both as an individual and through funding for your laboratory and department.

By design, interacting with OTD is a streamlined process, driven by a one-on-one relationship with an assigned business development contact. After you notify us of your invention, we provide expert assistance to protect and market it, leverage resources to advance it further, develop relationships with industry, contract with the best possible commercial partner, and monitor and enforce partnership agreements.

Taking advantage of our many services assures you of an efficient, savvy, and unbiased partner in technology development. 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. And our track record in launching impactful partnerships and ventures is among the best in the nation.

Harvard was ranked third among Thomson Reuters' 100 "Most Innovative Universities" worldwide in 2015.

What is intellectual property?

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 — for example, through a patent, copyright, and/or trademark — and it can be bought, sold, or licensed.

Whose property is it?

Under Harvard's Intellectual Property (IP) Policy, the University owns intellectual property that is generated through research conducted with the use of its facilities and resources.

What happens to the license revenues?

If IP commercialized by OTD generates royalties or other revenue above Harvard's out-of-pocket expenses to protect and license it ("Net Royalties" under the IP Policy), those who have created the IP (e.g., inventors or authors) personally receive a portion of those funds. The University uses the remainder to support additional research and academic programs, including in each creator's research lab, department, and School.

Harvard's Intellectual Property Policy can be found at **www.otd.harvard.edu**


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Corporate partnerships & collaborations

Harvard's primary source of research funding is the federal government, but cultivating new sources of support is essential. Industry sponsorship and research collaborations can offer a bridging strategy to advance early-stage technologies toward commercial partnership, while in the meantime adding value to the funded technology.

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.

Corporate partners may sponsor research in your lab, helping you advance your work in a single area of mutual interest, or they may enter a strategic alliance with the wider University. Our strategic alliances fund the work of multiple investigators over the course of several years to make progress on broad, complex challenges.

We take great care not to limit inventors' rights to publish and present their research results. We understand the culture of both industry and the university, so we are able to craft thoughtful agreements that meet the needs of all parties, protect academic freedom, and help advance research and innovation.

We recommend that you familiarize yourself with University policies (including the IP Policy), as well as school-specific policies relating to the performance of sponsored research and the management of conflicts of interest and/or commitment.

Accelerators

Academic research is often viewed as being at too early a stage to attract interest from venture investors or from companies that would develop it further. Moreover, federal funding and other conventional grants rarely support the kind of proof-of-concept research needed to de-risk university technologies.

To help bridge this development gap, OTD has established two accelerator programs. The Blavatnik Biomedical Accelerator and the Physical Sciences & Engineering Accelerator provide highly focused grant funding to help promising technologies reach the next development milestone at which an industrial partner will engage. Accelerator funding of faculty research frequently leads to industry sponsorship, licensing, or the launch of a startup.

Harvard's two pioneering accelerators have become model programs for other universities around the world.

The **Blavatnik Biomedical Accelerator** works in consultation with an independent advisory committee of leaders from Harvard and the Boston life sciences community. Awards are typically in the range of $100,000 to $300,000, and approximately half of the projects funded in the past have led to industry partnerships. An important complementary program for the Blavatnik Biomedical Accelerator is the Blavatnik Fellowship in Life Science Entrepreneurship at Harvard Business School, which engages recent MBA graduates in the practice of technology commercialization, especially through new venture creation.

An analogous program, the **Physical Sciences & Engineering Accelerator**, provides slightly smaller awards and has shown tremendous success at launching new startups since its creation in 2013.

Applications are reviewed on an annual basis.


REPORT
& PROTE
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The first critical step to commercializing any invention is to inform OTD, so that we can help you protect it.

Contact OTD when you believe you have a scientific or technical discovery with potential for partnering or commercial development, and well before publicly disclosing your observations or publishing a manuscript. Once an invention has been disclosed through a publication, conference presentation, poster session, job talk, or other presentation to non-Harvard participants, the possibility of patent protection outside the United States can be significantly limited.

OTD recognizes that publishing and scientific discussion are of paramount importance, and when addressed at an early stage, IP can be protected while these activities remain unhindered.

After you report your invention to us through our online form, we evaluate it for patentability and marketability.

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 commercialized so that it can provide its maximum benefit to society.

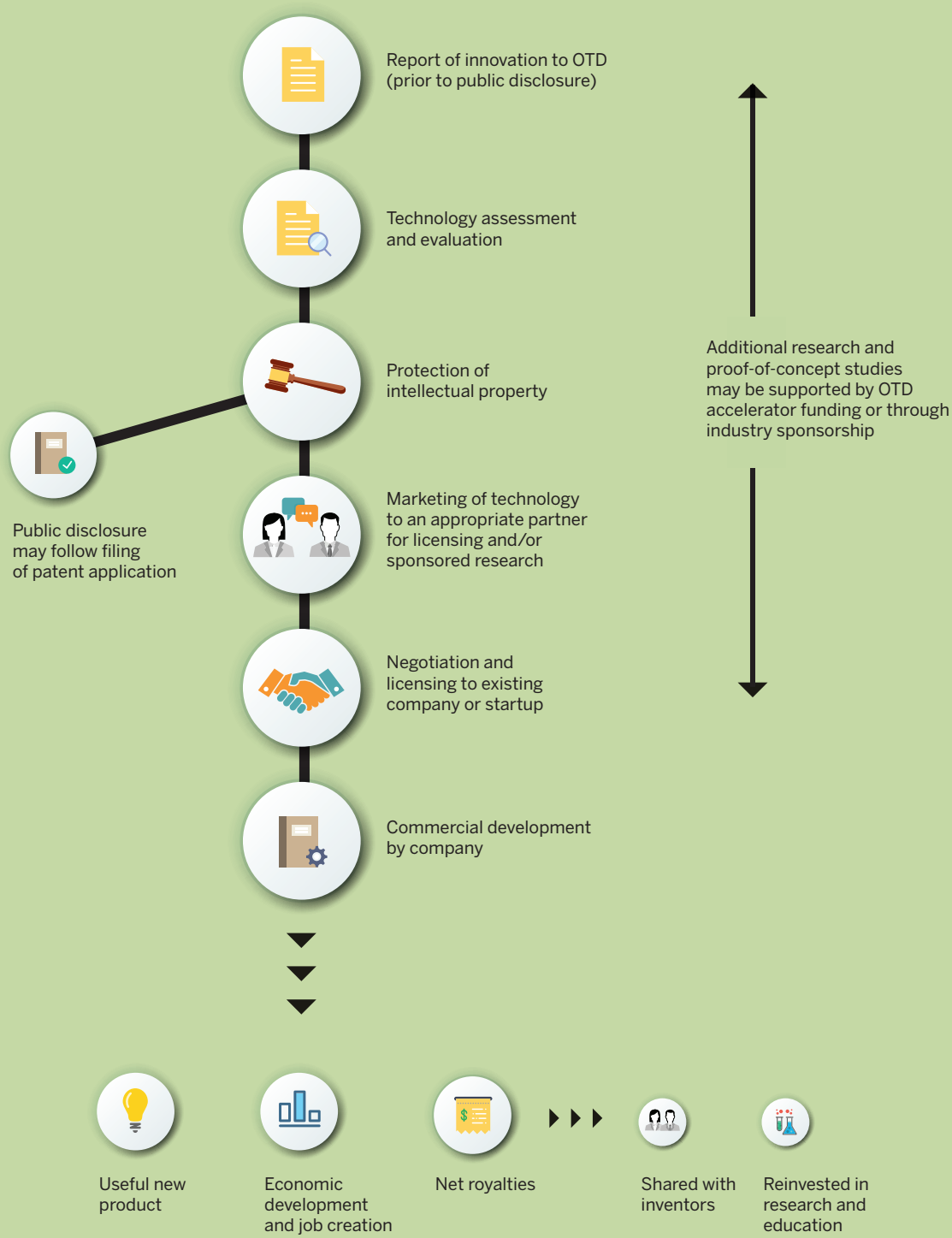
In addition to initiating commercialization, reporting inventions is the crucial first step to required reporting of new inventions arising from federal or private-sponsor funding.

How to report an invention

The reporting procedure is accomplished through a simple Report of Innovation 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.

OTD has created a secure and easy-to-use online ROI tool. You can access the tool on our website at www.otd.harvard.edu.

Technology development 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.

Patentable subject matter includes:

- **Compositions of matter** — new chemical or biological entities, but not isolated products of nature
- **Machines** — mechanical or electronic devices, including medical devices
- **Articles of manufacture** — new products made by defined process
- **Processes** — methods of making compositions, methods of making articles, and even some methods of gathering or evaluating data or of performing business.

Harvard researchers generate other types of intellectual property in addition to inventions, such as copyrightable creations, including content-based scholarly works, and unpatented materials, such as cell lines.

Who is an inventor?

Inventorship is a legal determination made by a patent attorney. An inventor on a patent 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. 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 or postdocs who carried out work in the lab, and collaborators or others who contributed to the invention.

When you report an innovation to OTD, you should err on the side of inclusiveness when naming contributors to the work, so that our attorneys can evaluate their possible inventive roles.

Patents

Depending on various technical and business factors, it may be desirable to seek legal protection for an invention to enhance its chances of benefiting society, the inventor, and the University. A patent is the surest means to protect an invention.

A patent prevents others from importing, making, using, or selling an inventor's intellectual property in the U.S. 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 will provide 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.

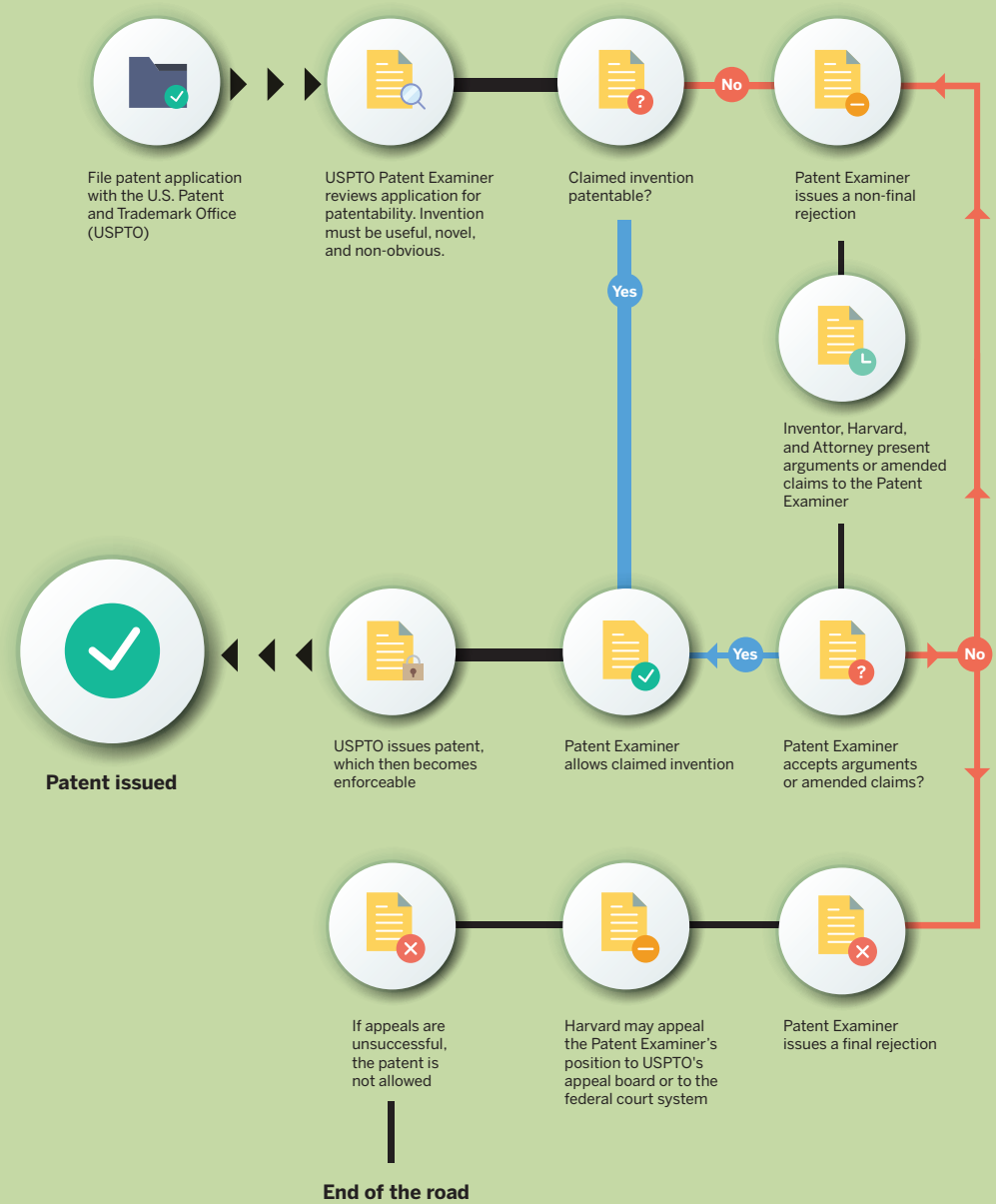
A novel invention may include known features, and a new use for existing processes or products may meet the standard for novelty. The novelty of an invention can be adversely affected by premature disclosure, or by undue delay of its disclosure.

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.

Roadmap for typical U.S. patent prosecution

To preserve patent rights internationally, and in most cases in the U.S., patent filing must occur prior to any publication or public disclosure.



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.

FIG. 6A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The "right" approach to commercialization depends largely on the technology and its stage of development. Most Harvard innovations that are disclosed to us are at a very early stage and need further development prior to commercial licensing — and that's okay. Industry collaborations and Harvard accelerator funding can help bridge the gap and validate technologies for particular applications.

Crafting a strategy

When the time comes, matching technologies with licensees and investors requires expertise, resources, and effective business networks. We will work with you to determine whether it is most appropriate to partner with an existing company or to create a startup. (In either case, the main transaction would be a licensing agreement.) Each approach has its advantages and challenges, and we will guide you toward a commercialization strategy that fits your invention.

In the life sciences, it is often (but not always) the case that the target market, application, investors, and a list of potential licensees may be relatively easy to define. For other technologies, such as a new microfluidic device or a surface coating, there may be multiple possible applications. Each industry may have its own economic model, manufacturing methods, and so forth. The business development challenge is to identify the most compelling application and the optimal path to commercialization.

OTD places a great deal of focus on developing effective strategies to commercialize Harvard IP. With your input and assistance, we will professionally "package" your invention, target it to the market, and determine the value proposition for the technology.

Identifying a partner

We will approach potential partners directly with a non-confidential marketing summary, showcase inventions at networking events and through digital outreach (e.g., website, newsletters, and social media), and leverage our extensive network. Our business development team has exceptionally strong contacts in industry and within the venture capital community.

We will then proceed to hold preliminary discussions and analyze the best path forward. As such discussions progress and a potential partner expresses a greater level of interest, we may organize in-depth meetings during which additional information is provided under confidentiality. These meetings frequently include scientific presentations by the inventors.

In tandem with this outreach, we do encourage you 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. However, it is important that you let us know sooner, rather than later, when you have initiated a discussion with industry.

The next step is to develop formal technology transfer agreements with a partner (or partners) that OTD determines to be well equipped and well positioned to commercialize the technology and maximize its impact. Based on the nature of the technology and other factors, the best partner may be either an existing company or a startup.

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.

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.

Startups

Launching a startup can be an exciting and fulfilling opportunity — however, only certain inventions may justify the formation of a new company. OTD can help you analyze several factors to determine whether this is the most appropriate path to commercialization, considering:

- The potential of the core technology to provide a solid platform for multiple markets or product opportunities
- The competitive environment
- Likelihood of interest from existing companies in licensing the technology
- Availability of venture capital, together with the interest, capabilities, and track record of likely investors
- Level of commitment of the inventor(s) to the commercialization process
- The presence of a true business "champion" for both the technology and the new venture
- The management team of the proposed startup

Startup 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

To learn more about forming a new company, ask for a copy of our Startup Guide.

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 corporate partner.

With careful planning, skilled management and well-structured agreements, Harvard researchers and industrial partners can collaborate for mutual, sustained benefit. Sample agreements are available for viewing on the OTD website.

The primary types of agreements negotiated by OTD include the following:

Confidentiality Agreements (CDAs) or **Non-Disclosure Agreements** (NDAs) with potential licensees and industry collaborators are used to protect the confidentiality of an invention, technology, or pre-publication information.

Research Collaboration Agreements (RCAs) or **Industry-Sponsored Research Agreements** (ISRAs) describe the terms under which sponsors provide research support for faculty-initiated research projects. Sponsors often perform a collaborative role in the research. OTD ensures that these agreements protect Harvard researchers' scholarly independence and right to freely publish their results.

Additionally, Harvard sometimes enters into longer-term **Strategic Research Alliances** with sponsors who fund multiple projects within a broad field of inquiry.

Inter-Institutional Agreements (IIAs) describe the terms under which Harvard and other research institutions will share financial, administrative, and other responsibilities of managing jointly owned intellectual property.

License Agreements enable the use of Harvard technologies in commercial applications. We require that licensees diligently seek to develop the licensed technology, for the benefit of the public, toward a commercial product, and our license agreements include specific development plans that set forth the steps a licensee will take to do so. The agreement terms set out various rights and responsibilities — for example, ensuring that the partnership will provide a fair and reasonable return to the University (via equity and/or royalties) and preserving the right of academic researchers to use the IP in further scholarly work.

Licenses to startups typically include equity as consideration for rights in Harvard IP. As an equityholder in these startup licensees, the University also enters into stockholder, registration rights, and other equity-related agreements as necessary.

Material Transfer Agreements are contracts governing the incoming or outgoing exchange of tangible research materials (including biological 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.

Option Agreements establish the conditions under which an industry partner will have the right to negotiate a license to Harvard IP. Typically, an option agreement precedes a full license agreement in order for an optionee to obtain funding or further evaluate a specific technology.

For each type of agreement, OTD makes certain that each party meets its obligations and remains on course.

WHO WE ARE

Your primary point of contact in OTD will be a member of our business development team whose technical and industry experience aligns with your research. He or she will develop a keen understanding of your laboratory's research program and will create a plan to advance and commercialize key projects and technologies.

Depending on your needs, such a plan might include industry funding, IP management, accelerator funding, licensing, venture creation, transactional support, and/or guidance on policy and compliance.

You will also be supported behind the scenes by teams handling Accelerators, Intellectual Property and Policy, Technology Transactions, Agreement Administration, and Corporate Alliances, as well as Finance, Administration, and Communications.

Stay connected

We encourage you to keep in touch with your colleagues' successes, helpful OTD resources, and networking events by joining our mailing list at otd.harvard.edu/mailing-signup.

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Let's talk!

If you have an idea to discuss, or if you have any questions, please contact us. OTD staff are always close by, with offices in Harvard Square, at Harvard Medical School, and at the Wyss Institute for Biologically Inspired Engineering.

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