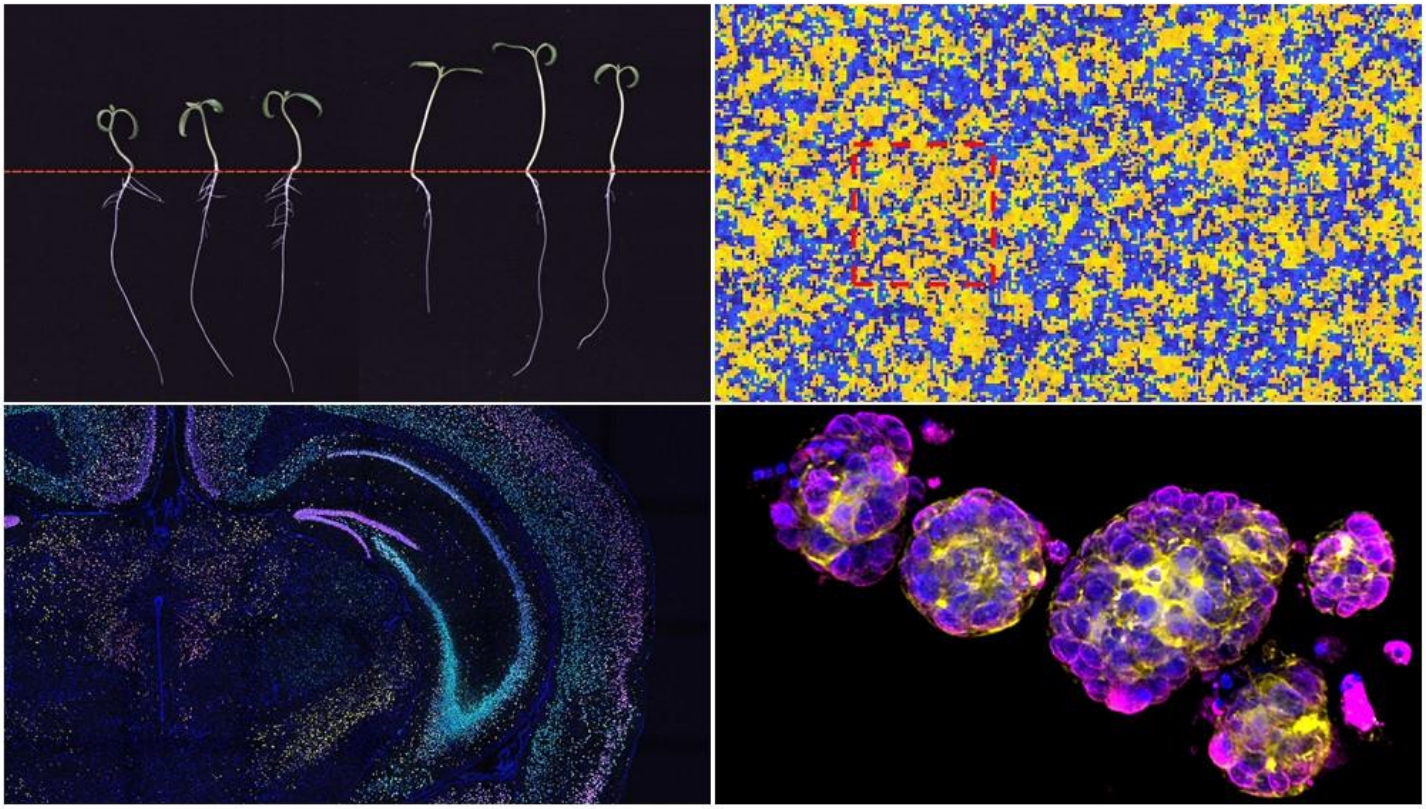
Scientist's Guide to Business Development & Technology Transfer at Cold Spring Harbor Laboratory



Cold Spring Harbor Laboratory

Scientist's Guide to Business Development & Technology Transfer at Cold Spring Harbor Laboratory

The Scientist's Guide outlines the essential elements of business development and technology transfer at Cold Spring Harbor Laboratory (CSHL).

The guide is organized to answer the most common questions we typically field from our research community and provides a broad overview of the technology transfer process and services available for CSHL scientists.

This guide is based on the University of Michigan Office of Technology Commercialization's "Inventor's Guide to Technology Commercialization" and Rockefeller University's "Information on Material Transfer Agreements." CSHL thanks the University of Michigan and Rockefeller University for permission to use their material.

The guide is available online at https://www.cshl.edu/partner-with-us/technology-transfer. Please visit our site, call the Office of Technology Transfer at 516-367-8301 or visit us in the Luke Building on the CSHL campus.

Cover Images (Clockwise from Top left): Plants depend on sunlight for photosynthesis. When they find themselves in too much shade, they will redirect their resources from root development towards stem growth, so they can grow taller and access the sun. In this image, the three plants on the left were grown in full unshaded light: they have lots of branched roots. In contrast, the three plants on the right were grown in the shade: they have less branched roots because the plant is focusing on growing a longer stem to try and reach more light. Image: Daniele Rosado/Pedmale lab

Much of the electrical activity in the brain looks like noise and is not associated with reactions to any particular stimuli. The scientists found that there was structure in the noise that could reveal the state of attentiveness in the brain. In this model of brain activity in the monkey visual cortex, the overall electrical activity was measured over time in each small area. Yellow and orange areas have high activity and blue areas have low activity, corresponding to "On" and "Off" states for a set of neurons. Researchers showed a monkey images across its entire field of vision, but like most of us, the animal paid attention (attended) to only a small part of that field. When the researchers looked closely, they could see waves of activity pass over the whole visual cortex, but the waves were faster and higher in the area corresponding to the attended part of the visual field. Image: Yan-Liang Shi/Engel lab

Organoids are tiny clumps of cells that are grown from and resemble tiny 3D organs. The image shows breast cancer organoids, derived from human patients. Breast cancer cells are labeled in purple, DNA is labeled in blue, and cytoskeleton proteins are labeled yellow. Organoids provide a more natural setting than flat tissue culture dishes to study how cancer cells grow, develop, and can be treated. Sonam Bhatia, Erika Wee/Spector lab

In this section of a mouse brain, BARseq2 detects RNA from dozens of genes in thousands of neurons. Each color lights up a different set of genes. Image: Xiaoyin Chen and Yu-Chi Sun/Zador lab

April 2022

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OVERVIEW

What is business development and technology transfer?

Business Development is the process of establishing and managing relationships with external companies and organizations to drive the processes of exploiting knowhow and IP developed at CSHL. Technology transfer is the formal and legal transfer of knowledge and discoveries to the public, usually through commercial contracts established through our business relationships. While academic pursuit traditionally shares knowledge through publications, educational seminars, exchanges at conferences, developing products or ideas that impact society typically require significant investment from external organizations. For the purposes of this guide, technology transfer refers to the formal licensing of technology and knowhow to third parties under the guidance of professionals employed by universities, research foundations, and businesses.

Why is CSHL involved in technology transfer?

CSHL leverages commercial channels as a means to carry out its mission of disseminating important discoveries for the benefit of the public.

How is technology transferred?

Technology and rights to knowhow are typically transferred through a license agreement in which CSHL grants its rights in the defined technology to a third party for a period of years, often limited to a particular field of use and/or region of the world. The licensee (the third party licensing the technology) may be an established company or a new business start-up.

Licenses include terms that require the licensee to meet certain performance requirements and to make financial payments to CSHL. These payments are shared with the inventors or contributors to the technology and are also distributed to CSHL to provide support for further research, education, and participation in the tech transfer process. The percentage distributed to the various entities can be found in the CSHL Commercial Relations Policy at https://www.cshl.edu/wp-content/uploads/2020/04/Commercial-Relations-Policy-revised-Mar-2020.pdf.

What is the role of the Office of Technology Transfer?

The Office of Technology Transfer is responsible for managing the commercial relationships and intellectual property developed by CSHL scientists for the purpose of fostering productive relationships with industry and life science investors to bring discoveries to the benefit of society.

The tasks of the office include, but are not limited to, fostering access to funding for financing early stage ideas, technology disclosure assessments, patent preparation and prosecution, commercial market analysis, contract negotiations for licensing, alliance management, and post deal management.

How does the Office of Technology Transfer foster relationships with industrial partners?

The Office of Technology Transfer seeks to increase industrial relationships through four broad categories of activity:

- Raising the awareness of the faculty to the opportunities for and the mechanism of obtaining industrial support, including institutional funding of new ideas;
- Increasing the awareness of industry to CSHL's expertise, knowhow and intellectual property, faculty, and organization assets;
- Proactively seeking and effectively negotiating agreements with industrial partners; and
- Contributing to CSHL's strategic development in areas with implications for industrial collaborations.

Why would a researcher want to participate in the technology transfer process?

The reasons are unique to each researcher and may include:

- Introducing new ideas and products that enhance science and medicine;
- Making a positive impact on society;
- Feeling a sense of personal fulfillment;
- Achieving recognition and financial rewards;
- Generating additional laboratory funding;
- Meeting the obligations of a research contract;
- Attracting research sponsors;
- Creating educational opportunities for students and post-docs; and
- Linking students and post-docs to future job opportunities.

What is the Bayh-Dole Act?

The U.S. Bayh-Dole Act of 1980 allows universities and other non-profit institutions to have ownership rights to discoveries resulting from federally funded research, provided certain obligations are met. These obligations include making efforts to protect (when appropriate) and commercialize the discoveries, submitting progress reports to the funding agency, giving preference to small businesses that demonstrate sufficient capability, and sharing any resulting revenues with the inventors. The Bayh-Dole Act is credited with stimulating interest in technology transfer activities and generating increased research, commercialization, educational opportunities, and economic development in the United States.

It should be noted that the diversification of funding sources accessed by CSHL scientists, for example, foundations, scientific consortia also bring further obligations on commercial rights to work funded by those institutions. We seek to maintain Bayh-Dole Act like rights on other sources of funding, by negotiating contracts to ensure consistent application of rights; however, it cannot be guaranteed.

OWNERSHIP OF INTELLECTUAL PROPERTY

What is "intellectual property"?

Intellectual property refers to creations of the mind (such as inventions, literary and artistic works) that may be protected from being used without authorization under the patent, copyright, trademark, trade secret or other laws.

Who owns the intellectual property I create ?

Ownership depends upon the employment status of the creators of the invention and their use of CSHL facilities and other resources. Considerations include:

- What is the source of the funds or resources used to produce the invention?
- What was the employment status of the creators at the time the intellectual property was made?
- What are the terms of any agreement related to the creation of the intellectual property?

As a general rule, CSHL owns intellectual property made or created by the faculty, students, staff, visitors, employees, volunteers, and others participating in CSHL programs while acting within the scope of their employment or using CSHL funds, facilities, or resources.

Who owns rights to discoveries made while I am consulting?

The ownership of intellectual property created while consulting for an outside company depends on the terms of your consulting contract. It is important to clearly define the scope of work within consulting contracts to minimize any issues with ownership of intellectual property arising from CSHL research. If you have questions, the Office of Technology Transfer staff and General Counsel can provide template language.

Should I list visiting scientists or scientists at other institutions on my Technology Evaluation/Disclosure?

All contributors to the ideas leading to a discovery should be mentioned in your **Technology Evaluation/Disclosure**, even if they are not CSHL employees. The Office of Technology Transfer, along with legal counsel, will determine the rights of such persons and institutions. It is prudent to discuss with the Office of Technology Transfer all working

relationships (preferably before they begin) to understand the implications for any subsequent inventions or other intellectual property.

Can a student contribute to intellectual property?

Yes, students, research technicians and other staff may work on research leading to intellectual property at CSHL. CSHL owns inventions made or created by the faculty, students, staff, visitors, employees, volunteers, and others participating in CSHL programs while acting within the scope of their employment or using CSHL funds, facilities, or other CSHL resources.

What is knowhow?

In the context of intellectual property, knowhow is a component in the transfer of a technology and can be defined as *closely held* information in the form of unpatented inventions, formulae, designs, drawings, procedures and methods, together with accumulated skills and experience in the hands of a CSHL personnel which could assist a licensee. It can be further supported with expert knowledge on the operation, maintenance, use, and application of a product and of its sale, usage or disposition.

LEGAL PROTECTIONS

Legal protection for technology

There are 2 main and interconnected means of protecting technology:

1. Legal agreements
2. Filing of patents

Certain inventions can also benefit from copyrights protection, particularly in software development.

Legal Agreements or Contracts

Protection for commercial ideas and technology come in the form of legal agreements or contracts that define the relationship between CSHL and a commercializing entity and 'sell' the rights to the technology in exchange for current and future financial consideration. CSHL is typically very active in developing relationships with commercial companies, often well in advance of the actual filing of patents. With early stage idea generation, it typically requires investment to validate the approach. CSHL seeks to access this type of investment funding through structures like Sponsored Research or Seed capital Agreements to allow continued development of ideas. In these circumstances it is important to protect the ideas that underpin technology, and this licensing of knowhow forms a key part of the Contract to ensure that actual products emerging from early ideas are recognized in future product development.

Patents

It is highly desirable where possible for CSHL to file strong patents to protect breakthrough inventions made by CSHL scientists. The rules of patenting are stringent and have changed in recent years in a way that has changed what intellectual property and technology, and the extent that intellectual property and technology can be protected by patenting.

What is a patent?

In the United States, patents are granted by the United States Patent and Trademark Office (USPTO). The main section of a patent is called the "specification," which contains a written description of the claimed invention telling what the invention is, how it works, how to make it, and how to use it. The specification concludes with one or more numbered sentences called patent claims, which define the boundaries of the legally protected inventions.
Although rights may vary from country to country, in general, a patent gives the holder the right to exclude others from making, using, selling, offering to sell, and importing the patented invention, without the patent holder's permission. Because it represents a "right to exclude," a patent does not necessarily provide the holder any affirmative right to practice a technology; that practice may fall under a broader patent(s) owned by others. A patent has two major components: (a) the "specification" (a technical discussion about the invention and how to practice it); and (b) the "claims" (the legal definition of an inventor's protectable invention).

What type of subject matter can be patented?

Things that are patentable include new, non-obvious and useful processes, machines, compositions of matter, manufactured items, articles, and methods such as methods for manufacturing items and materials.

Patentable subject matter includes processes, machines, compositions of matter, articles, some computer programs, and methods (including methods of making compositions, methods of making articles, and even methods of performing business). The type of inventions that are patentable vary from country to country.

There are a number of explicit exclusions on patentable matter that are determined by case law and the patent office. In the context of work done at CSHL, these would include any naturally occurring compositions, even if they have not been described before, including genes and gene products. The emphasis in patents is not on the function of an invention, rather on the physical components of an invention.

What is the United States Patent and Trademark Office (USPTO)?

The USPTO is the federal agency, organized under the Department of Commerce, which administers patents on behalf of the government. The USPTO employs patent examiners skilled in all technical fields in order to appraise patent applications. The USPTO also issues federal trademark registrations.

What is the definition of an inventor on a patent, and who determines this?

Under U.S. law, an inventor is a person who takes part in the conception of any invention claimed in the patent application. Inventorship depends only on the claims and not any other text included in the body of the patent application (or issued patent). Therefore, inventorship of a patent application may change as the patent claims are changed during the application process. Inventorship and conception both have strict legal meanings. Inventorship is not the same as authorship and determining inventorship will require analysis by a patent attorney. Inventorship is also not the sole determination of distribution of income from an invention, which can be wider and involve other staff who participate in providing rights and knowhow in agreements.

Who is responsible for patenting?

The Office of Technology Transfer contracts outside patent counsel for IP protection, thus assuring access to patent specialists in diverse technology areas. CSHL's outside patent counsel are responsible for drafting the patent applications and communicating with the patent examiners during the application process, which is often referred to as prosecution. The Office of Technology Transfer staff help manage the patent prosecution process, including selection and oversight of the outside patent counsel, including oversight of patent filings and prosecution.

What is the patenting process?

Patent applications are drafted and filed by a patent attorney or a patent agent (a non-attorney with a science education licensed to practice by the USPTO). To draft the application, the patent attorney generally will work closely with you and Office of Technology Transfer staff, including CSHL's in-house patent counsel. As part of the process, the patent attorney will review the contribution of each person involved in the underlying work to determine who should be named as an inventor. Before an application is submitted to the USPTO, each named inventor should review the application and, if there are any questions, should be sure to discuss them with Office of Technology Transfer staff and the patent attorney. When the application is filed, all CSHL inventors are required by USPTO rules to sign an Inventor's Declaration and also a confirmatory Assignment, confirming that the inventors have assigned the patent to CSHL.

Once a national stage patent application has been filed in the U.S., it usually takes from one to two years for the USPTO to issue an initial assessment of the patentability of what is being claimed. Rejections may be based either on certain formalities that need to be addressed, or on any reason why the claims have not met the legal standards for

patentability, for example, that the claimed invention is not adequately described in the patent application, or that the claims are not patentable over the "prior art" (any information in the public domain, such as publications, talks, or other published patent filings) or "insufficient description" of the invention in the specification to support the claims. The letter sent by the USPTO is referred to as an "Office Action" or "Official Action."

If the application is rejected, the patent attorney must file a written response, usually within three to six months. Generally, the attorney may amend the claims and/or point out why the USPTO's position is incorrect. Ordinarily, it will take at least two USPTO Official Actions and two responses by the patent attorney – and in the area of biotechnology often many more – before the application is resolved. The resolution can take the form of a USPTO notice that the application is "allowable" – in other words, the USPTO agrees to issue a patent. This process is referred to as "patent prosecution." During this process, the patent attorney may request input from the inventors to better understand technical aspects of the invention and/or prior art cited against the application. Generally, patent applications remain confidential for 18 months from the filing date of the priority application, which is usually the provisional application filing date.

What is a provisional patent application?

In the U.S., the USPTO provides two options when filing a utility patent, one called a provisional filing and the other called a non-provisional filing. The main difference between the two is that a provisional application is not examined by any patent office.

Why file a provisional patent application as opposed to a regular ("nonprovisional" or "utility") patent application?

In certain circumstances, U.S. provisional patent applications can provide a tool for preserving patent rights by establishing a "priority date" for an invention while postponing the cost of filing a non-provisional application, which ordinarily at CSHL would be a PCT application. Importantly, to establish the priority date for any invention, the provisional application must satisfy the same legal standards for patentability as would be required for a non-provisional application. In other words, the provisional application must demonstrate the applicant actually possessed the invention as of the filing date, and among other things, must describe the invention in enough detail for someone of ordinary skill in the art to make and use the invention without undue experimentation. If the provisional application does not describe the invention thoroughly enough, it will fail to establish a priority date for patent claims directed to the invention when such claims are ultimately filed and examined in the U.S. and/or abroad. In short, under current patent law, the effort and cost of drafting a provisional application is no different than for a non-provisional application, and generally should include the full set of claims one intends to prosecute in the U.S. and abroad. A provisional application remains pending for only one year. Therefore, the decision as to whether to file a further PCT or U.S. application from the provisional application must be made before that deadline.

What's different about foreign patent protection?

A patent is enforceable only in the country in which it issues. U.S. patents, for example, are not enforceable outside the U.S. Foreign patent protection is subject to the laws of each individual country, although in a general sense the process works much the same as it does in the U.S.

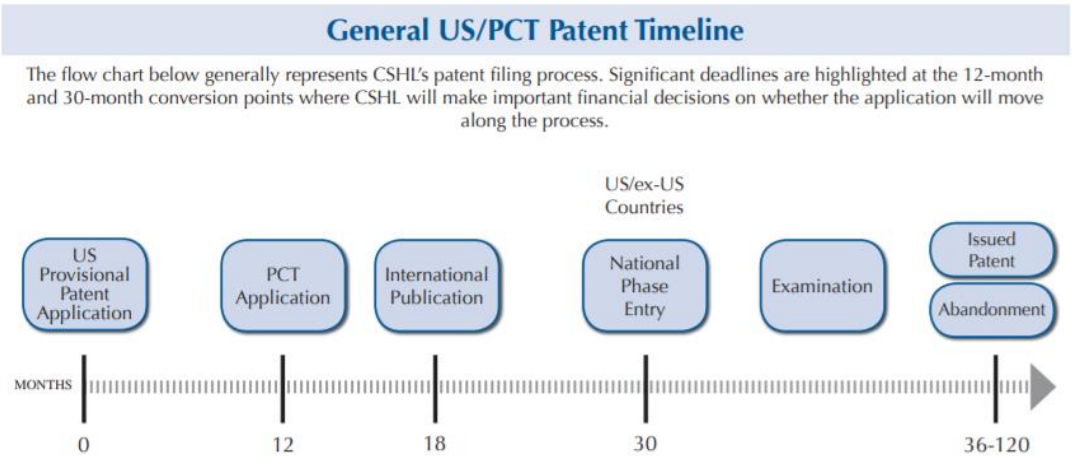
How does one obtain patents in other countries? Is there such a thing as an international patent?

Although an international patent does not exist, an international agreement known as the Patent Cooperation Treaty (PCT) provides a streamlined filing procedure for most industrialized nations. The best way to think about it is that while there are international patent applications, there is no such thing as an international patent. For U.S. applicants, a PCT application is generally filed one year after the corresponding U.S. application (usually a provisional) has been filed. The PCT application must later be filed in the national patent office of any country in which the applicant wishes to seek patent protection, generally within 30 months of the earliest claimed filing date.

While significantly more expensive than filing only a U.S. application, the PCT application provides two advantages. First, it delays the need to file costly foreign applications until the 30-month date, often after an applicant has the opportunity to further develop, evaluate and/or market the invention for licensing. And secondly, by using the PCT process, the time during which the provisional application was pending will not count against patent term, and therefore a patent when issued will effectively gain the benefit of an extra year of life.

What is the timeline of the patenting process and resulting protection?

Currently, the average U.S. utility patent application is pending for about two years, though inventors in the biotech and computer fields should plan on a longer waiting period. Generally, it will take from three to six years from the time a biotech patent application is filed in the U.S. for the Patent Office to decide to issue a patent, or in other words from about five to eight years after a provisional application is first filed. Once a patent is issued, it is generally enforceable for 20 years from the filing date of the initial application (usually a PCT application) that resulted in the patent, assuming that USPTO-mandated maintenance fees are paid.



Why does CSHL protect intellectual property through patenting?

Patent protection is can be a requirement of a potential commercialization partner (licensee) because it can protect the commercial partner's often sizable investment required to bring the technology to market. It is now also common that agreements are made on knowhow and breakthrough science before patents are filed. Due to their expense and the length of time required to obtain a patent, patent applications are not possible or appropriate for all CSHL intellectual property. We carefully review the commercial potential of a technology and likely patentability before investing in the patent process. In some cases, we need to patent before can find a licensee, and so we look for creative and cost-effective ways to secure early protections for as many promising inventions as possible.

Who decides what gets protected?

The Office of Technology Transfer staff and the contributing scientist(s) consider relevant factors in making recommendations about filing patent applications. The decision to file is based on the commercial potential of the technology being considered for patenting, patentability of the technology and ultimately the potential for positive societal impact on the public, as well as financial impact to CSHL. The final decision, as to whether to file a patent application or seek another form of protection, is made by the CSHL Vice President, Business Development and Technology Transfer based on input from CSHL scientists, external experts, outside patent attorneys and Office of Technology Transfer staff.

What does it cost to file for and obtain a patent?

Filing a provisional U.S. patent application that can effectively function to establish a filing date may cost between $20,000 and $50,000. Obtaining an issued patent in the U.S. only may require an additional $20,000 to $100,000 for patent prosecution. Filing and obtaining issued patents in Europe may cost anywhere from $40,000 to $150,000 per country. In other countries outside Europe, it costs about $30,000 or more per country. Obtaining

patent rights in all the major world markets will therefore commonly require between $250,000 and $500,000. Once a patent is issued in the United States or in foreign countries, maintenance fees are required to keep the patent in force.

What if I created the invention with someone from another institution or company?

If you created the invention under a sponsored research or consulting agreement with a company, the Office of Technology Transfer staff will need to review the contract to determine ownership and other rights associated with the contract and to determine the appropriate next steps. Should the technology be jointly owned with another academic institution, the Office of Technology Transfer staff will usually enter into an "inter-institutional" agreement (IIA) that provides for one of the institutions to take the lead in protecting and licensing the invention, sharing of expenses associated with the patenting process, and allocating any licensing revenue. If the technology is jointly owned with a company, the Office of Technology Transfer staff will work with the company to determine the appropriate patenting and licensing strategy.

Will CSHL initiate or continue patenting activity without an identified licensee?

Often CSHL accepts the risk of filing a patent application before a licensee has been identified. After CSHL's rights have been licensed to a licensee, the licensee generally pays the patenting expenses. At times we must decline further patent prosecution after a reasonable period (often a year or two) of attempting to identify a licensee, or if it is determined that we cannot obtain reasonable claims from the USPTO.

What is a copyright and how is it useful?

Copyright is a form of protection provided by the laws of the United States to the authors of "original works of authorship." This includes literary, dramatic, musical, artistic, and certain other intellectual works, as well as computer software. This protection is available to both published and unpublished works. The Copyright Act generally gives the owner of copyright the exclusive right to conduct and authorize various acts, including reproduction, public performance, and making derivative works. Copyright protection is automatically secured when a work is fixed into a tangible medium such as a book, software code, video, etc. In some instances, CSHL registers copyrights, but generally not until a commercial product is ready for manufacture.

What is a derivative work?

A "derivative work" is a work based upon one or more preexisting works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgment, condensation, or any other form in which a work may be recast, transformed or adapted. A work consisting of editorial revisions, annotations, elaborations, or other modifications, which, as a whole, represent an original work of authorship, is a "derivative work." The owner of a copyright generally has the exclusive right to create derivative works.

How do I represent a proper CSHL copyright notice?

Although copyrightable works do not require a copyright notice, we recommend that you use one. The following notice is to be applied on CSHL owned works to protect the copyright:

> "Copyright © 20XX Cold Spring Harbor Laboratory. All rights reserved."

The date in the notice should be the year in which the work is first embodied or published. No notice other than the foregoing is to be used for CSHL owned works.

For additional copyright protection, certain works should be registered with the United States Copyright Office using its official forms.

If you have any questions about copyright notices and registration, please contact the Office of Technology Transfer or the Office of the General Counsel.

What is a trademark or service mark, and how is it useful?

A trademark includes any word, name, symbol, device, or combination, that is used in commerce to identify and distinguish the goods of one manufacturer or seller from those manufactured or sold by others, and also to indicate the source of the goods. In short, a trademark is a brand name. A service mark is any word, name, symbol, device, or combination that is used, or intended to be used, in commerce to identify and distinguish the services of one provider from those of others, and to indicate the source of the services.

A trademark or service mark may be used to protect those names and symbols associated with certain CSHL activities and events, and with certain technology developments such as computer programs. Prior to registration for trademark protection, the designation "TM" after a trademark or "SM" after a service mark will give adequate notice of a claim of ownership. The designation "®" for a trademark may only be used after federal registration. Registration of trademarks and service marks may be used to protect CSHL owned technology or to designate CSHL as the origin of a product, event, activity, service, or the like. It is important to note that trademark protection comes with certain obligations on the part of the holder of the mark. Therefore, requests for use and registration of trademarks or service marks on behalf of CSHL must be referred to the Office of Technology Transfer which will engage CSHL Public Affairs as appropriate.

What is trademark registration?

Trademark registration is a procedure in which the United States Patent and Trademark Office (USPTO) provides a determination of rights based upon legitimate use of the mark. However, it is not necessary to register a trademark to prevent others from infringing upon the trademark. Trademarks generally become protected as soon as they are adopted by an organization and used in commerce, even before registration. With a federal trademark

registration, the registrant is presumed to be entitled to use the trademark throughout the United States for the goods or services for which the trademark is registered.

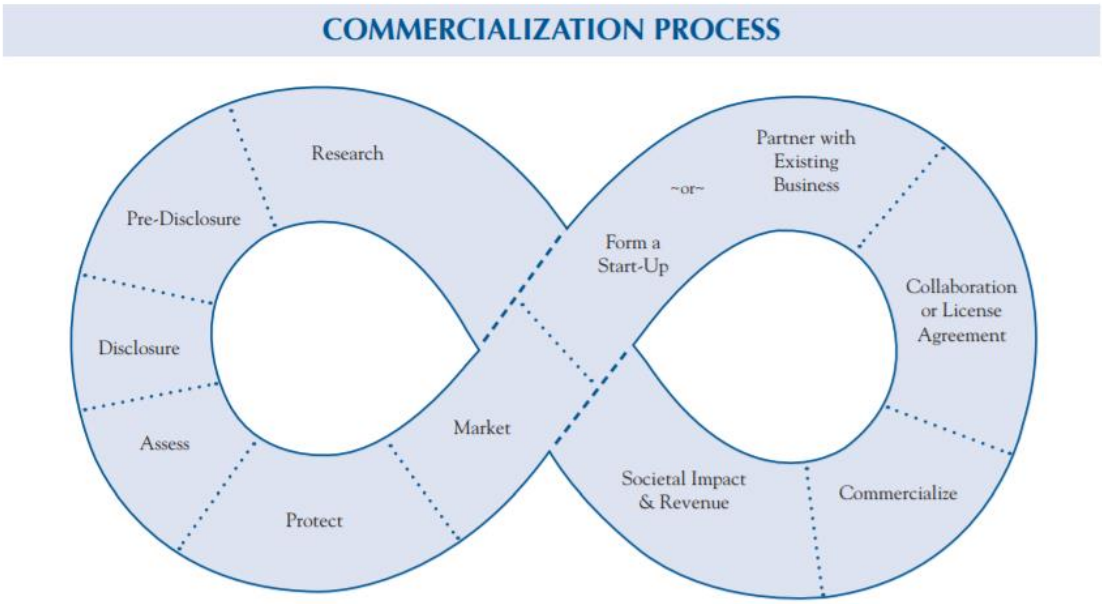
THE TECHNOLOGY TRANSFER PROCESS

How do I work with the Office of Technology Transfer?

We encourage you to contact the Office of Technology Transfer during your early research activities to be aware of the options that will best leverage the commercial potential of your research. The Office of Technology Transfer staff are ready to assist you with questions related to marketability, funding sources, commercial partners, patenting and other protection methods, new business start-up considerations, CSHL policies and procedures, and much more.

What are the typical steps in the process?

The process of technology transfer is summarized in the steps and diagram that follow. Note that these steps can vary in sequence and often occur simultaneously.



1) Research:

   Observations and experiments during research activities often lead to discoveries and inventions or technologies. An invention is any new and useful process, machine, composition of matter, or any new or useful improvement of these. Often, multiple researchers may have contributed to the invention.

2) Pre-Disclosure:

An early contact with the Office of Technology Transfer staff to discuss your discovery and to provide guidance with respect to the disclosure, evaluation, and protection processes described below. Prior to contacting the Office of Technology Transfer staff, it can be helpful if you consider the following questions:

- What is this technology? What does it do and what problems does it solve?
- Is anyone else working on this? How does your work compare? How would your advantage(s) be demonstrated/evidenced (i.e. clinical study end point)?
- What features of your discovery are distinguished from others?
- Has the technology been, or are there plans for it to be, presented or published? Is there a thesis involved? Where and when and in how much detail was it presented/discussed?
- Is there a company or companies that would want to commercialize this? Why would they find it valuable?
- What are the immediate obstacles faced? What are the next milestones? Is there more work to be done (questions to be answered) before a company would find this technology of interest?
- How was this work funded? Who sponsored this work? Do we have obligations to this (these) sponsor(s)?

3) Technology Disclosure:

The written record of the technology to the Office of Technology Transfer begins the formal technology transfer process. A technology disclosure remains a confidential document and should fully document your discovery and the contributions of each individual listed on the disclosure so that the options for commercialization can be evaluated and pursued.

4) Assessment:

The period in which you and a member of the Office of Technology Transfer staff review the technology disclosure, conduct patent searches (if applicable), and analyze the market and competitive technologies to determine commercialization potential of the discovery.

This evaluation process, which may lead to a broadening or refinement of a prospective invention or technology, will guide whether to focus on an option through an industry collaboration, license to an existing company, or creating a new business start-up.

5) Pre-Marketing and Establishing Early Funding:

Ideas emerging from academic work seldom provide a final solution or product for commercialization. During the Assessment phase, consideration will be given to gaining support for the initial work by consultation with external experts in the field, which could include venture capitalists, business leaders and or companies. In this period, careful protection of the ideas will be completed, usually under the protection of a Non-Disclosure Agreement between the parties. Many times, the relationships developed from these early disclosures of potentially valuable ideas, can lead to sourcing of new funds to advance the validation of the inventions, such as Sponsored Research in the lab of the inventor. CSHL has institutional agreements in place for this type of work, and can provide introductions to expert groups to evaluate inventions.

6) Protection and Marketing:

The process in which intellectual property protection for an idea is pursued, Patent protection, a common legal protection method, begins with the filing of a patent application with the U.S. Patent and Trademark Office (USPTO) and, when appropriate, foreign patent offices. Once a patent application has been filed, it typically will require several years and hundreds of thousands of dollars to obtain issued U.S. and foreign patents. Other protection methods include copyright, trademark, trade secrets, and contractual use restrictions (e.g., for databases and materials).

With your active involvement, the Office of Technology Transfer staff identifies candidate companies that have the expertise, resources, and business networks to bring the technology to market. This may involve partnering with an existing company through a research collaboration or license, or forming a start-up. Your active involvement can dramatically shorten and enhance this process.

7a) Existing Business:

If a suitable and interested existing company, or companies, are selected as a potential collaborator or licensee, the Office of Technology Transfer will work with those potential licensees to develop the appropriate financial and diligence terms to commercialize the technology.

7b) Form a Start-up:

If creation of a new business start-up has been chosen as the optimal commercialization path, the Office of Technology Transfer will work on connecting you to business formation consultants or others as needed to assist in planning, forming, and funding the start-up.

8) Licensing:

A license agreement is a contract between CSHL and a third party in which CSHL's rights to a technology are licensed, without relinquishing ownership, for financial and other benefits. A license agreement is used with both an established company as well as

a new start-up business. An option agreement is sometimes used to enable a third party to evaluate the technology for a limited time prior to deciding about licensing, to allow the start-up business to attract management and raise money before completing the license – or it may be a component of a collaborative research arrangement between CSHL and an established company.

9) Commercialization:

The licensee continues the advancement of the technology and makes other business investments to develop the product or service. This step may entail further development, sponsored research at CSHL, regulatory approvals, sales and marketing support, training, and other activities.

10) Revenue:

Revenues received by CSHL from licenses are distributed among the contributors to the technology as well as CSHL to fund additional research and education and to encourage further participation in the technology transfer process. The exact distribution is cited in the Cold Spring Harbor Laboratory Commercial Relations Policy.

How long does the technology transfer process take?

The process of protecting the technology and finding the right licensing partner may take months – or even years – to complete. The amount of time will depend on the development stage of the technology, the market for the technology, competing technologies, the amount of work needed to advance a new concept to market-ready status, and the resources and willingness of the licensees and the inventors. The value that is returned to CSHL and the inventors may take place over decades, and so building high quality relationships with commercialization companies is critical to success in these endeavors.

Who are the Office of Technology Transfer staff?

The CSHL Office of Technology Transfer is comprised of experienced legal, business, and support staff who work closely with other CSHL departments, including the Offices of Sponsored Programs/Grants, Development, General Counsel, and Public Affairs, to support you when engaging with industry in order to obtain the greatest impact from your discoveries.

How can I help in this process?

- Call the Office of Technology Transfer at 516-367-8301 or email a member of the technology transfer team when you believe you have created or discovered something unique with potential commercial value or a research tool of broad interest.

- Talk to the Office of Technology Transfer if you have questions before you start an external collaboration. It is important to have a contractual agreement if the external collaboration is with industry and we can help establish an agreement before you proceed with the collaboration.

- Complete and submit the **Technology Evaluation/Disclosure Form** long before publicly disclosing your technology or submitting a manuscript for review and publication. Generally, public disclosure acts as a bar to filing for and obtaining patent protection. Note that submitting the Technology Evaluation/Disclosure Form is the first step in considering patent protection; it is not the same as filing a patent application.

- To avoid risking your patent rights and possibly hindering the opportunity to partner your invention, contact the Office of Technology Transfer before holding any discussions with people outside of CSHL.

- On the **Technology Evaluation/Disclosure** form, include companies and contacts you believe might be interested in your invention or who may have already contacted you about your invention. Studies have shown that over 70% of all licenses are executed with commercial entities known by the scientist, so your contacts can be extremely useful.

- Respond to the Office of Technology Transfer and outside patent counsel requests. Some aspects of the patent and licensing process may require significant participation on your part. We and our outside patent counsel, however, will strive to make efficient use of your valuable time.

- Keep the Office of Technology Transfer staff informed of upcoming publications or interactions with companies related to your intellectual property.

RESEARCH CONSIDERATIONS

Will I be able to publish the results of my research and still protect the commercial value of my intellectual property?

Yes, but since patent rights are affected by these activities, it is best to submit a Technology Evaluation/Disclosure well before communicating or disclosing your invention to people outside of CSHL. In general, patent protection is precluded by any public disclosure. Be sure to inform the Office of Technology Transfer of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/master's thesis, publication including bioRxiv, or other public presentation that describes or refers to a new technology or discovery with potential commercial value.

May I use material or intellectual property from others in my research?

Yes, but it is important to document carefully the date and conditions of use so that we can determine if this use may influence the ownership and license rights of your subsequent research results. If you wish to obtain materials from outside collaborators, an incoming Material Transfer Agreement (MTA) should be completed. Contact the MTA Coordinator in the Office of Technology Transfer at 516-367-8301 or techtran@cshl.edu for more information on incoming MTAs.

Will I be able to share materials, research tools, or intellectual property with others to further their research?

Yes. However, it is important to document items that are to be shared with others and the conditions of use. If you wish to send materials to an outside collaborator, an outgoing Material Transfer Agreement (MTA) should be completed for this purpose. It also may be necessary to have a Confidentiality Agreement completed to protect your research results or intellectual property. Contact Office of Technology Transfer staff or the MTA Coordinator in the Office of Technology Transfer (516-367-8301 or techtran@cshl.edu) to assist you in completing outgoing MTAs or Confidentiality Agreements.

What rights does a research sponsor have to any discoveries associated with my research?

The Sponsored Research Agreement (SRA) should specify the intellectual property (IP) rights of the sponsor. CSHL generally retains ownership of the patent rights and other intellectual property resulting from sponsored research. However, the sponsored research contracts often allow the sponsor a limited time to negotiate a license for any patent or intellectual property rights developed as a result of the research and specific to the scope and funding of the research (an "option). The sponsor generally will not have contractual rights to discoveries that are clearly outside of the scope of the research or that were invented prior to the research term. Therefore, it is important to define the scope of work within a research agreement and to review the IP provisions in the research contract.

Who at CSHL handles research agreements?

The Office of Technology Transfer handles sponsored research projects with industry or others which require licenses to patents or other intellectual property created during the project. If you have questions about sponsored research, please contact the Office of Technology Transfer or the Office of Sponsored Programs/Grants at osp@cshl.edu.

What About Consulting?

When researchers enter into consulting agreements, they are deemed to be acting outside of the scope of their CSHL employment. Researchers who enter into consulting agreements should familiarize themselves with CSHL's policies relevant to consulting activities. The researcher is expected to ensure that the terms of the consulting arrangement are

consistent with CSHL's policies, including those related to employment responsibilities as well as use and ownership of intellectual property.

The Office of Technology Transfer is available to provide informal advice on how your consulting agreement relates to your CSHL Intellectual Property; and CSHL's General Counsel reviews all faculty consulting agreements to ensure that they are consistent with institutional policies and have followed the proper CSHL review and approval process. A sample consulting template is available from the Office of Technology Transfer or the General Counsel.

TECHNOLOGY DISCLOSURES

What is a Technology Disclosure?

A Technology Disclosure is a written description of your invention or development that is provided to the Office of Technology Transfer. The first step in pursuing potential commercialization of a Technology generated at CSHL is for the Investigator to complete a **Technology *Evaluation* Form** (https://www.cshl.edu/wp-content/uploads/2020/11/Technology_Evaluation_Form.pdf) for early review of the Technology with the Office of Technology Transfer. If a commercial application is identified, a **Technology *Disclosure* Form** (https://www.cshl.edu/wp-wcontent/uploads/2020/11/Technology_Disclosure_Form.pdf) will be completed to assist in compiling information necessary for any patent filings and/or government or foundation reporting and disclosure obligations. The Technology Evaluation/Disclosure forms should list all collaborators, the contributions of each, and sources of support; ideally, it should also include all of the information necessary to begin pursuing protection, marketing, and commercialization activities. Please attach any draft manuscripts or pending grant proposals in order to simplify the process.

These documents will be treated as "CSHL Confidential." Based on the Technology Disclosure, the Office of Technology Transfer staff may work with you to generate a non-confidential description of your technology in order to assist in marketing the technology. Once potential partners have been identified, and confidentiality agreements have been signed, more detailed exchanges of information can be made.

Why should I submit a Technology Evaluation/Disclosure?

When you disclose your discovery to the Office of Technology Transfer, it starts a formal process that could lead to the protection and commercialization of your technology. This may involve beginning the process of filing for patent protection and/or working to identify outside development partners. If government funds were used for your research, you are required to file a prompt disclosure, which will be reported by the Office of

Technology Transfer to the sponsoring agency. Similar requirements may exist for other sponsored projects.

You are encouraged to submit a **Technology Evaluation/Disclosure** form for all inventions and developments that you believe may solve a significant problem and/or have significant value. While Technology in the form of Intellectual Property is often financially most valuable, Research Assets, such as know-how, and Tangible Research Property can also represent significant commercial value as components of commercial deals, and can often open opportunities for commercial partnerships. If you are in doubt, contact your Office of Technology Transfer representative to discuss your discovery and strategies for commercialization.

When should I complete a Technology Evaluation/Disclosure form?

You should complete a **Technology Evaluation/Disclosure** form whenever you feel you have discovered something unique that may have commercial value. This should be done well before presenting the discovery through publications, poster sessions, conferences, press releases, or other communications. Once publicly disclosed (i.e., published or presented in some form), an invention may have limited or no potential for patent protection. Be sure to inform the Office of Technology Transfer of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal, dissertation/master's thesis, publication, or other public presentation including the invention.

Should I disclose research reagents?

Yes, if your new reagents would benefit other researchers and you are interested in providing them to those researchers and other third parties. Typically, research reagents are materials such as antibodies, vectors, plasmids, cell lines, mice, rats and other materials used as "tools" in the research process. Most research reagents do not necessarily need to be protected by patents in order to be licensed to commercial third parties and/or generate revenue for your laboratory. If you have research reagents that you believe to be valuable, or wish to provide to others (including research collaborators), the Office of Technology Transfer will work with you to develop the appropriate protection, licensing, and distribution strategy.

Should I disclose drug/therapeutic targets?

Though targets are not patentable in themselves, small molecules, peptides, or antibodies to targets may be. You are encouraged to disclose your work on promising well-characterized targets early on to allow the Office of Technology Transfer to work with you to help identify opportunities for collaboration and commercialization.

How do I submit a Technology Evaluation/Disclosure?

First, complete a **Technology *Evaluation* Form**. If you have any questions, call the Office of Technology Transfer at 516-367-8301 or e-mail us at techtran@cshl.edu If a commercial application is identified, we would request a Technology Disclosure Form to be completed.

ASSESSMENT OF A TECHNOLOGY DISCLOSURE

How does CSHL assess new technologies?

Office of Technology Transfer staff examine each newly reported technology to consider a wide range of issues relevant to commercialization, including whether, or the extent to which it can be protected by patent or other legal protection, marketability of potential products or services, relationship to related intellectual property, size and growth potential of the relevant market, amount of time and money required for further development, pre-existing rights associated with the technology, and potential competition from other products/technologies. This assessment may also include consideration of whether the technology can be the basis for a new business startup.

Each technology disclosure will be reviewed by Office of Technology Transfer staff with input from the inventor(s) and external resources considering obligations to research sponsors, commercial interest from potential licensees, research collaborators or investors, and scope of intellectual property protection relevant to commercial use.

If the inventors believe that their invention (all IP) should be licensed non-exclusively to all potential users for the public good, will CSHL honor our request?

The Office of Technology Transfer will work with you to develop the appropriate commercialization strategy for the invention. Some technologies lend themselves to non-exclusive licensing (licensing to multiple third parties), while others will only reach the commercial marketplace, and therefore the public, if they are licensed on an exclusive basis. We will always try to accommodate inventors' commercialization wishes. However, the final decision should be determined by which strategy will produce the most benefits for the public, consistent with governmental or institutional policies and other obligations.

How do we decide whether to commercialize with a traditional or an "open source" license for software?

Generally, the Office of Technology Transfer supports CSHL software developers who choose to distribute their programs through open-source mechanisms at no charge, provided that CSHL retains the right to distribute the program as well, that open sourcing is consistent with obligations to sponsors, and that each developer's laboratory supports the decision.

Is an invention ever assigned to an Inventor?

If the Office of Technology Transfer decides not to pursue patent protection and/or chooses not to actively market the technology, CSHL may transfer ownership to the scientist(s) making the Technology Disclosure. Reassignment of inventions funded from U.S. government sources requires the inventor to petition the funding agency and obtain approval for reassignment, based on agency guidelines.

TRANSFERRING MATERIALS

The transfer of materials and research tools is an essential part of scientific research. When a paper is published, the scientist must often provide the material to fellow researchers in order for others to repeat the experiment and verify the results. A Material Transfer Agreement (MTA) is the legal contract between CSHL and the party to receive or that will provide the materials, used to define the terms and conditions for the exchange of materials.

Why are MTAs essential?

MTAs are essential to protect:

- Publication rights
- Intellectual property rights
- Against liability to other parties.

When the material is of a unique or proprietary nature, the provider may wish to control how the material is used and limit its further distribution.

An MTA typically sets forth rights to use the materials and may control rights to the results of their use. Often MTAs address such issues as publication, limitations on the use of the materials, and the intellectual property rights of the provider and the recipient parties in inventions arising from the use of the material.
Given that money is rarely associated with these transfers, MTAs may be perceived by some to be inconsequential transactions. However, they are binding legal agreements that can impact a researcher's current and future research.

MTAs are processed through the Office of Technology Transfer. In order for us to process MTAs in a timely manner, please alert our office to the need for one as early as possible, well before the materials are required, as MTAs may require time to negotiate.

Types of MTAs for requesting or providing materials:

1) Academic/Non-profit

2) Company/For-profit (usually requires more time to negotiate than an MTA with an academic/non-profit)

Under what circumstances are MTAs needed?

MTAs are needed in most circumstances whenever a material is traveling out from CSHL to another party, or traveling in from another party to CSHL.

What MTA terms and conditions frequently pose problems for acceptance by CSHL?

CSHL will typically not accept terms that:

- Restrict academic freedom, such as restrictions on publication
- Assert excessive rights of ownership in the research results or derived materials
- Ask for inappropriate indemnification by CSHL and/or create conflicting obligations (with sources of funds or materials)

Is it reasonable to charge fees for the transfer of material?

While the majority of MTAs occur without any associated fees, some MTAs do include a nominal charge to the recipient in order to offset the costs incurred by the provider in preparing and shipping the material (or animal).

Who has the authority to sign an MTA?

MTAs are legally binding agreements between CSHL and the party providing or sending the material. Therefore, they must be signed by the CSHL Vice President for Business Development & Technology Transfer, the General Counsel, or Patent Counsel. It is important to be aware that the CSHL faculty member sending or receiving the material is not a party to the MTA and the faculty member has no power to bind CSHL to a legal agreement by signing the agreement. However, faculty are asked to sign MTAs as "read and acknowledged" to ensure that the terms accurately reflect the needs of the scientist's laboratory and that the scientist is aware of and understands the terms of the MTA.

What is CSHL's position on MTAs?

The Office of Technology Transfer will prepare outgoing MTAs and review incoming MTAs as a service to the research community and to mitigate risks for CSHL.

FINDING A LICENSEE

How are most licensees or collaboration partners found?

Studies have shown that many licensees were already known to scientists with the inventive idea. Thus, research and consulting relationships are often a valuable source of licensees. Licensees are also identified through existing relationships of the Office of

Technology Transfer staff. We attempt to broaden these relationships through contacts obtained from website posting inquiries, market research, industry events, and the cultivation of existing licensing relationships.

How long does it take to find a potential licensee?

It can take months and sometimes years to locate a potential licensee or industrial partners, depending on the attractiveness of the technology, its stage of development, competing technologies, and the size and intensity of the market. Most CSHL technologies tend to be in the early stage of the development cycle and thus require substantial commercialization investment, making it difficult to immediately attract a licensee.

How can I assist in partnering my technology/marketing my invention?

Your active involvement can dramatically improve the chances of matching a technology to an outside company. Your research and consulting relationships are often helpful in both identifying potential licensees and technology champions within companies. Once interested companies are identified, the scientist is the best person to describe the details of the idea and its advantages. The most successful technology transfer results are obtained when the scientist and the Office of Technology Transfer staff work together as a team to market and sell the technology.

Can there be more than one licensee?

Yes, a technology can be licensed to multiple licensees, either non-exclusively to several companies or exclusively to several companies, each for a unique field-of-use (application) or geography.

LICENSES AND OTHER AGREEMENTS

What is a license?

A license is a permission that the owner or controller of technology, including intellectual property rights in that technology, know-how and materials grants to another party, usually under a license agreement.

What is a license agreement?

License agreements describe the rights and responsibilities related to the use and exploitation of technology and intellectual property rights developed at CSHL. CSHL license agreements usually stipulate that the licensee should diligently seek to bring the technology into commercial use for the public good and provide a reasonable return to CSHL.

How is a company chosen to be a licensee?

A licensee is chosen based on its ability to commercialize the technology for the benefit of the general public. Sometimes an established company with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a start-up company is a better option. It is rare for CSHL to have multiple potential licensees bidding on a technology (invention).

What can I expect to gain if my IP is licensed?

Per CSHL policy, a share of any financial return from a license is provided to the contributors list on the Technology Disclosure. Most inventors enjoy the satisfaction of knowing their technology is being deployed for the benefit of the public. New and enhanced relationships with businesses are another outcome that can augment one's teaching, research, and consulting. In some cases, additional sponsored research may result from the licensee.

What is the relationship between a scientist and a licensee, and how much of my time will it require?

Many licensees require the active assistance of the scientist to facilitate their commercialization efforts, at least at the early stages of development. This can range from infrequent, informal contacts to a more formal consulting relationship. Working with a new business start-up can require substantially more time, depending on your role in or with the company and your continuing role within CSHL. Your participation with a start-up or any consulting agreement with a licensee is governed by CSHL conflict-of-interest policies, the approval of your supervisor, and the approval of the CSHL President.

What other types of agreements and considerations apply to technology transfer and are administered by the Office of Technology Transfer?

- **Non-Disclosure Agreements (NDAs)**, also known as **Confidential Disclosure Agreements (CDAs)**, are often used to protect the confidentiality of an invention or technology during evaluation by potential licensees. NDAs also protect proprietary information of third parties that CSHL researchers need to review in order to conduct research or evaluate research opportunities. The Office of Technology Transfer enters into NDAs for CSHL proprietary information shared with someone outside of CSHL.

- **Material Transfer Agreements (MTAs)**, used for incoming and outgoing materials at CSHL, are administered by the Office of Technology Transfer. These agreements describe the terms under which CSHL researchers and outside researchers may share materials, typically for research or evaluation purposes. Intellectual property rights can be endangered if materials are used without a proper MTA.

- **Inter-Institutional Agreements (IIAs)** describe the terms under which two or more institutions (generally two academic research institutions) will collaborate to assess, protect, market, license, and share in the revenues received from licensing jointly owned intellectual property.

- **Option Agreements**, or **Option Clauses** within research agreements, describe the conditions under which CSHL preserves the opportunity for a third party to negotiate a license for intellectual property. Option clauses are often provided in a Sponsored Research Agreement to corporate research sponsors or Option Agreements are entered into with third parties wishing to evaluate the technology prior to entering into a full license agreement.

- **Sponsored Research Agreements (SRAs)** describe the terms under which sponsors provide research support to CSHL. When a company is the sponsor, these are negotiated by Office of Technology Transfer in cooperation with the Office of Sponsored Programs/Grants.

COMMERCIALIZATION

What activities occur during commercialization?

Most licensees continue to develop an invention to enhance the technology, reduce risk, prove reliability, and satisfy the market requirements for adoption by customers. This can involve additional testing, prototyping for manufacturability, durability and integrity, and further development to improve performance and other characteristics. Documentation for training, installation, and marketing is often created during this phase. Benchmarking tests are often required to demonstrate the product/service advantages and to position the product in the market.

What is my role during commercialization?

Your role can vary depending on your interest and involvement, in the interest of the licensee in utilizing your services for various assignments, and any contractual obligations related to the license or any personal agreements.

What revenues are generated for CSHL if commercialization is successful?

Most licenses have licensing fees that can be very modest (for start-ups or situations in which the value of the license is deemed to warrant a modest license fee)—or can reach hundreds of thousands of dollars. Royalties on the eventual sales of the licensed products can generate revenues, although this can take years to occur. Equity, if included in a license, can yield returns, but only if a successful equity liquidation event (public equity offering or a sale of the company) occurs. Patenting and licensing early discoveries is risky and as a

result, most licenses do not yield substantial revenues and most investment in patent protection is not recovered.

A recent study of licenses at U.S. universities demonstrated that only 1% of all licenses yield over $1 million. However, the rewards of an invention reaching the market often go beyond financial considerations alone.

What will happen to my invention if the start-up company or licensee is unsuccessful in commercializing the technology? Can the invention be licensed to another entity?

Licenses typically include performance milestones that, if unmet, can result in termination of the license. This termination allows for subsequent licensing to another business. While licensees usually can terminate at will, generally CSHL is only able to terminate if the licensee is not performing under the agreement.

REVENUE AND EQUITY DISTRIBUTIONS

How are license revenues distributed?

The Office of Technology Transfer is responsible for managing the expenses and revenues associated with technology agreements. Per the CSHL Commercial Relations Policy, revenues from license fees, royalties, and equity – minus any unreimbursed patenting and related expenses – are shared with inventors.

What are the tax implications of any revenues I receive from CSHL?

License revenues are typically taxed as Form 1099 income. You should consult a tax advisor for specific advice.

What happens to my share of licensing revenue if I waive rights to it?

Revenues waived by inventors are distributed to CSHL for research and educational purposes. To avoid potential tax liability, revenues waived by you to your department/institute must not be under your control.

How are inventor revenues distributed if there are multiple inventors and/or multiple inventions in a license?

In the case where a license involves a technology with multiple inventors, authors, or contributors or involves multiple technologies or patents, the Office of Technology Transfer will request the contributors to the Technology Disclosure to propose, from their perspective, a fair and equitable distribution of revenue among the contributors. If the contributors can achieve an agreement, they will submit a Royalty Distribution Form signed by each one of them to the Vice President, Business Development & Technology

Transfer, stating their agreement and providing the specific income distribution scheme. This distribution will be recommended to the President, who will make the final decision on distribution. In the event that such agreement cannot be achieved, the President will make the determination.

What is equity?

Equity is defined as an ownership interest in a company, including but not limited to: shares of stocks, warrants, options, convertible instruments, and participation as a partner in a partnership.

What if I receive equity (stock) from a company?

Under CSHL Policy, scientists who receive equity from a licensee or other company doing business with CSHL are required to report this as described in the conflict of interest policy.

How is equity from a license distributed?

When equity is part of the payment for a technology license, it is shared with the inventors or contributors the same way as other license revenue. It can be shared as equity (issued to the relevant individuals at the time it is issued more broadly) or distributed as cash when the equity is realized and becomes cash. If CSHL acquires the equity through investment of cash or as a founder, distribution will be at the discretion of the CSHL President.

CONSIDERATIONS FOR A START–UP COMPANY

What is a start-up company, and why choose to create one?

A start-up is a new business entity formed to commercialize one or more related technologies. Forming a start-up company is an alternative to licensing the IP to an established business. A few key factors when considering a start-up company are:

- Availability of start-up management and investment (is there management and investors willing to go at risk with the company);
- development risk (often companies in established industries are unwilling to take the risk);
- development costs versus investment return (can investors obtain their needed rates of return);
- potential for multiple products or services from the same technology (few companies survive on one product alone);
- sufficiently large competitive advantage and target market; and
- potential revenues sufficient to sustain and grow a company.

The Office of Technology Transfer can help evaluate these and other factors.

Who decides whether to form a start-up?

The choice to establish a new company for commercializing IP is a joint decision made by the Office of Technology Transfer, the contributors to the Technology Disclosure, and the CSHL President. If a new business start-up is chosen as the preferred commercialization path, the Office of Technology Transfer will assist you in planning and executing the process.

What start-up assistance and resources are available to CSHL scientists?

Office of Technology Transfer staff can serve as coaches, advisors, resource locators, and project planners to help fill the gap between the technology and the formation of a start-up. Their activities may include locating prospective management talent, developing a funding strategy, making introductions to probable investors, reviewing business plans, and engaging experts to work on key gating issues. CSHL is often recognized as a founder and equity is provided to the Lab in recognition of this support; equity may also be provided as a term under the license.

Can I be a consultant in a company that I start?

CSHL scientists can consult for companies that they start. However, CSHL scientists must follow the guidelines in the CSHL Commercial Relations Policy.

Under what conditions will CSHL license to a start-up?

Office of Technology Transfer staff have an obligation to license only to those companies with the resources to commercialize the asset that is being entrusted to it. The start-up must have a business plan, management, and resources appropriate for the license commitment

What are the license terms like when CSHL licenses to a start-up?

The license terms are standard terms for the industry the start-up is in and may include license fees, patent costs, milestone payments, and royalties on sales of products. Depending on the industry, royalties can range from 1%-10% of sales of products or services. With start-ups, the license fees are often made in the form of equity instead of cash. For example, if the up-front license fee is typically $500k for an exclusive license in the field, then the equity would be for $500k based on the valuation at the time of the license.

What role does a CSHL scientist usually play in a company?

CSHL scientists typically serve as technology consultants, advisors or in some other technical developmental capacity. CSHL does not allow faculty to serve as employees of the company as it is seen as an unmanageable conflict. In many cases, the faculty role is suggested by the start-up investors and management team, who identify the best role based on the inventor's expertise and interests.

As the company matures and additional investment is required, the scientist's role may change. Faculty involvement of any kind in a start-up is also reviewed by CSHL's General Counsel as it relates to CSHL conflict-of-interest policy. Student inventors (upon graduation) and post-docs may choose to join the start-up, but rarely have the experience or business skills to serve as company's sole management.

How much of my time and effort will it take?

Starting a company requires a considerable amount of time and effort. Until the start-up team is identified and engaged, the scientist will need to champion the formation effort. After the team is in place, effort is required for investor discussions, formal responsibilities in or with the company, and CSHL processes such as conflict of interest reviews.

Can CSHL accept equity in the company?

CSHL can accept equity as part of the financial terms of the license, as a founder or in rare instances as an investor. Equity may be substituted for other cash considerations that are often difficult for start-ups. It is also a way for CSHL to share some of the risk associated with the start-up. A decision to take equity must make sense for both CSHL and the company.

Will CSHL pay for incorporating a start-up company?

Generally, no. As a separate entity, the start-up should pay for its own legal matters, including all business incorporation and licensing expenses.

Can the start-up manage the patents licensed to it?

CSHL may allow a company to engage directly with patent counsel regarding the CSHL IP licensed to it. This is done through a three way agreement among the company, CSHL, and a law firm recognizing CSHL as the client and the Company as the entity lead for communication and responsibility for costs.

What legal assistance is needed in creating a start-up company?

In addition to corporate counsel, the start-up may have its own intellectual property counsel to assist with corporate patent strategy, especially if the company will be involved in a patent-rich area. The start-up's counsel must be separate from CSHL counsel, though it is advisable and recommended that the corporate IP Counsel and the Office of Technology Transfer staff coordinate activities. Also, it is wise for founding scientists to have

agreements regarding their roles with the start-up reviewed by their own counsel to ensure that all personal ramifications—including taxation and liabilities—are clearly understood.

NAVIGATING CONFLICT OF INTEREST

How does CSHL define a conflict of interest?

A conflict of interest can occur when a CSHL employee, through a relationship with an outside organization, is in a position to: 1) influence CSHL's business, research, or other interests that may lead to direct or indirect personal financial gain, 2) adversely impact or influence research or teaching responsibilities, or 3) provide improper advantage to others, to the disadvantage of CSHL.

When should I seek guidance on conflict of interest?

Whenever a question or uncertainty arises, you should seek guidance from CSHL's Office of Sponsored Programs/Grants for Federal and foundation funded research-related issues and/or the General Counsel or Office of Technology Transfer representatives for license-related issues. For additional information about conflicts of interest, please see Chapter 4 of CSHL's Commercial Relations Policy.

What kinds of issues concern conflict of interest reviewers?

Conflicts of interest can pose many risks, including appropriate and objective conduct of research, the treatment and roles of students, supervision of individuals working at CSHL, and conflict of commitment (i.e., your ability to meet your CSHL obligations).

Another issue of potential concern is **Consulting for a Research Sponsor**. A for-profit sponsor of CSHL's research may also seek to establish a separate consulting arrangement with an employee of CSHL. This may be permitted provided the consulting agreement is not an integral part of the sponsored research relationship. To ensure this is the case, the Consulting Agreement must be reviewed and approved in advance by the General Counsel and CSHL Administration, and the Financial Conflict of Interest Committee must first establish a management plan that mitigates any risks arising from the sponsored research arrangement.

What are examples of a conflict of commitment?

A conflict of commitment may exist if duties, assignments, or responsibilities associated with a technology license or outside business arrangement (e.g., consulting) have a negative impact on your ability to meet commitments associated with your CSHL employment, or exceed the amount of allowable time available to you for these activities.

The best approach is to fully disclose your proposed arrangement to your supervisor and discuss the implications for your job responsibilities.

How does CSHL manage possible conflicts of interest associated with research and technology transfer transactions?

Office of Technology Transfer staff can advise you on conflict-of-interest issues or direct you to the Conflict of Interest and Compliance Coordinator within CSHL. It is the responsibility of the scientist to disclose and document any outside arrangements as described in **CSHL's Investigator Conflict of Interest Policy** (https://www.cshl.edu/wp-content/uploads/2020/11/Investigator_Conflict-of-Interest_Policy.pdf).

REINVESTMENT AND RELATIONSHIPS

Every year, the Office of Technology Transfer, working with CSHL scientists and business Partners, facilitates a growing portfolio of technology disclosures, patent applications, options, licenses, sponsored research, and other enabling agreements. These agreements are measures of commitment to advance innovation at CSHL and achieve commercialization of those research results.

This activity generates annual revenues that are shared among CSHL, its scientists, and partnering institutions. These revenues are reinvested in additional research and education, thus fostering innovative research as well as the next generation of researchers and entrepreneurs.

In addition, the resultant relationships created and deepened through these activities support CSHL's mission. They result in additional research projects, broader educational opportunities and collaborative investments, and an enhanced ability to create, retain, and share valuable resources that contribute to our quality of life.

Common Acronyms

CDA: Confidential Disclosure Agreement

COI: Conflicts of Interest

CSHL: Cold Spring Harbor Laboratory

IIA: Inter-Institutional Agreement

IP: Intellectual Property

MTA: Material Transfer Agreement

NDA: Non-Disclosure Agreement

PCT: Patent Cooperation Treaty

SRA: Sponsored Research Agreement

USPTO: United States Patent and Trademark Office

Important CSHL Contact Information

Office of Technology Transfer
Phone: 516-367-8301
E-mail: techtran@cshl.edu
Website: https://www.cshl.edu/partner-with-us/technology-transfer/
Location: Luke Building, 2nd Floor, CSHL

Office of Sponsored Programs/Grants
Phone: 516-367-6835
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