

COMMERCIALIZATION GUIDE



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*“Either write things worth reading, or do things worth the writing.”
— Benjamin Franklin*



OVERVIEW

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What is university technology commercialization?

University technology commercialization, sometimes known as technology transfer, involves the creation of business relationships between the university and the commercial sector for the purpose of creating products and services based on discoveries invented at the university. The Penn Center for Innovation (PCI) facilitates business relationships with the private sector that often conclude with formal contractual

agreements that grant commercial development rights to Penn-owned technology, copyrights, or materials. These relationships take the form of licensing deals, industry partnerships, and/or startup company formation that incentivize their further commercial development, while also fully preserving academic freedom and publishing rights for University researchers.

Why should a researcher consider participating in the technology commercialization process?

Successful technology commercialization can result in significant benefits for both universities and their participating faculty, which may include:

- Generating new sources of funding and new collaborative partners for researchers and their labs;
- Helping to create and foster a vibrant culture of entrepreneurship that promotes recruitment and retention of faculty;
- Increasing student interest and success through participation in applied research, education about

the patenting and licensing process, and increased job prospects;

- Addressing global challenges in health, the environment, and technology;
- Economic development benefits via reinvestment of licensing revenue in additional research, multi-institutional grants, industry partnerships, talent retention, start-up companies, and new job creation; and
- Potentially significant licensing revenues and/or equity value.

What is the Bayh-Dole Act?

The Bayh-Dole Act of 1980 provides universities with the right to assert ownership rights to inventions made by their employees using federal funds and mandates that universities make reasonable efforts to translate potential discoveries into useful products and services via licensing of technology to the private sector. The Bayh-Dole Act requires universities that assert ownership to inventions created using federal funding to share royalties on such inventions with inventors and to use the net income earned from such invention to support scientific research or education.

What is the Penn Patent Policy?

The Penn Patent Policy, described in much greater detail in Section 6 of this handbook, defines the respective rights and obligations of the university and its employees as it pertains to the creation and commercialization of inventions at Penn. Pursuant to the Patent Policy, Penn owns the inventions created at Penn by Penn personnel (which includes faculty, post-docs, and grad students supported by research grants) and actively manages the licensing rights to the technology, while also taking direct responsibility for the protection and maintenance of patents.

How is PCI different from its predecessor, the Center for Technology Transfer (CTT)?

Most major universities have technology commercialization practices that focus predominantly on patenting and licensing. As Penn has become more involved in advancing technologies into the development sphere, the University has engaged more actively in complementary activities such as new venture creation and collaboratively sponsored research projects with industry. Through the creation of PCI, Penn combined all of these related activities into a one-stop shop for the benefit of our faculty, staff, and students.

What is the role of PCI at the University?

Every day, research activities at Penn result in exciting scientific breakthroughs and technological advances that may have significant commercial potential. PCI's goal is to work together with Penn faculty, staff, and students to advance these discoveries and ideas towards new products, services, and/or businesses that provide benefits back to Penn, its inventors, and society. PCI also supports the broader innovation and entrepreneurship community at Penn through education, programs and events, and active support and participation in the Pennovation Center and Pennovation Works project.

WHAT IS THE PENN CENTER FOR INNOVATION (PCI)?

The Penn Center for Innovation consolidated and unified the University's office of technology transfer (formerly known as CTT) with other Penn commercialization resources devoted to the advancement of Penn research and development towards the product marketplace, allowing for a more streamlined experience for Penn researchers and potential business and industry partners. The Center's website (www.pci.upenn.edu) provides step-by-step instructions and other personalized resources for individuals ranging from student, staff, and faculty inventors to entrepreneurs and venture capitalists. Maximizing the ability of Penn researchers to effectively collaborate with the private sector is one of Penn's highest goals as clearly articulated in Penn Compact 2020, the University's strategic vision authored by President Amy Gutmann. Penn Compact 2020 revolves around three major strategic aims for the university: inclusion, innovation, and impact. PCI helps Penn to achieve two of these three vital goals at once by helping to provide Penn innovations and inventors with the best chance to impact the world at large.

How does PCI provide services to faculty inventors?

PCI's model facilitates an efficient and comprehensive service for faculty through a variety of means, including:

- established satellite offices embedded within client schools so that PCI's licensing officers are easily accessible to faculty and are able to respond quickly and collaboratively to commercialization opportunities that arise;
- an online invention disclosure portal that makes it easy for faculty to get the commercialization process started with PCI: <http://bit.ly/pcidisclosures>;
- active marketing outreach leveraging the information available via PCI's technology database: <http://upenn.technologypublisher.com/> and relationships developed through PCI's licensing staff and Corporate Outreach group;
- extensive new venture creation resources via PCI's Venture's team: www.pci.upenn.edu/pciventures/; and other resources: www.pci.upenn.edu

How does PCI help to promote a culture of innovation and entrepreneurship at Penn?

PCI offers numerous programs and educational events throughout the year targeted toward different stakeholders in the Penn community and the wider Philadelphia entrepreneurial ecosystem to help better establish Penn as the go-to place for innovation.

Some recent examples:

- PCI's Innovation & Entrepreneurship speaker series featuring industry experts as well as Penn faculty and staff. Past topics have included Forming a Startup at Penn, Patenting 101, Leveraging Early Stage Funding, and University-Industry Partnerships.
- The Penn I-Corps Site Startup Accelerator. This NSF (National Science Foundation) program is designed to facilitate commercialization of university research. PCI invites up to 30 teams per year to participate in the program.
- The Pennovation Center. This new facility is an innovation hub, business incubator, and laboratory on the Pennovation Works site that stimulates entrepreneurial activity and promotes the commercialization of research discoveries. PCI works closely with the Pennovation Center team to provide educational programs for members and the broader Philadelphia community.



“An investment in knowledge pays the best interest.”
— Benjamin Franklin

The background of the top half of the page features a close-up of a fingerprint on the left and a portion of a US dollar bill on the right. The fingerprint is rendered in a light grey tone, while the dollar bill is in a golden-yellow hue. The text 'INVENTION DISCLOSURES' is overlaid on this background, with 'INVENTION' in red and teal, and 'DISCLOSURES' in blue and yellow.

INVENTION DISCLOSURES

WHAT IS AN INVENTION DISCLOSURE?

An invention disclosure is a formal written description of an invention or development that is provided to PCI. Detailed instructions on how to submit a Penn invention disclosure are available here: <http://bit.ly/pcidisclosures>. The disclosure should list all sources of support and include all of the information necessary to begin pursuing protection, marketing, and commercialization activities. Based on the invention disclosure and inventor input, PCI may generate a non-confidential description of the invention 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 submit an invention disclosure?

Penn's Patent Policy requires invention disclosures so that Penn may assess inventions for potential commercialization and meet its obligations to government and other funding sources. When you disclose an invention to PCI, it starts a process that could lead to the patenting and/or commercialization of the technology. The commercialization process often involves initiating the legal and patent protection process and working to identify outside development partners. If government funds were used for your research, additional information must be reported to the sponsoring agency. Similar requirements often exist for other types of sponsored projects.

How do I submit an invention disclosure?

You can submit an invention disclosure using the Inventor Portal or with an Invention Disclosure Form. Both can be found on PCI's website at <http://bit.ly/pcidisclosures>

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WHEN SHOULD I COMPLETE AN INVENTION DISCLOSURE?

*You are **required** to submit an invention disclosure for any potentially patentable invention or discovery if you used federal funds or sponsored research funding, and you are encouraged to submit a disclosure for all other inventions and developments that you feel may solve a problem and/or have value. Submitting a disclosure should ideally occur well before presenting the discovery through publications, abstracts, poster sessions, conferences, press releases, or other communications. Presentation or publication of an invention in any form before filing for patent protection may restrict or eliminate the ability to obtain a patent, particularly outside of the United States. Be sure to inform PCI of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal, dissertation/thesis, publication, or other public presentation that includes the invention. If you are ever in doubt or have any questions, please don't hesitate to contact PCI for further discussion.*



*"The doors of wisdom are never shut."
— Benjamin Franklin*



INTELLECTUAL PROPERTY

PATENTS

What is a patent?

In the United States, the owner of an issued patent has the right to exclude others from making, using, selling, offering to sell, and importing the patented invention. This right is not automatic and may need to be actively enforced or defended by the patent owner. A patent does not provide the owner with any right to practice a technology that falls under a broader patent owned or controlled by others. The specific claims of an issued patent define the legal scope of the owner's protectable invention.

What type of subject matter can be patented?

Patentable subject matter includes processes, machines, compositions of matter, articles, some computer programs, and methods (including methods of making compositions, methods of using a process or material, etc.).

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

The USPTO is the federal agency, organized under the Department of Commerce, which administers the patent system on behalf of the government of the United States. The USPTO employs patent examiners skilled in all technical fields in order to evaluate 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 the invention(s) claimed in the patent application. Accordingly, inventorship may change as the patent claims are changed during prosecution of the application. A person who only furnishes the funds to build or practice an invention, or is directed by another to perform a specific task or series of tasks, is generally not an inventor. The appropriate inventors on a patent application are determined by a registered patent attorney.

Who is responsible for patenting?

PCI contracts with external patent counsel for the protection of inventions owned by the university, thus assuring access to skilled patent specialists across a wide range of technology areas. Inventors typically work collaboratively with patent counsel in drafting the patent applications and formulating responses to patent office questions and feedback. PCI selects and oversees outside patent counsel.

What is the patenting process?

Patent applications are generally drafted by a patent attorney or a patent agent (a non-attorney with a science education licensed to practice by the USPTO). The patent attorney will typically ask you to review an application before it is filed and will also ask you questions about inventorship of the invention(s) claimed in the application. At the time an application is filed with the USPTO, the patent attorney will ask the inventor(s) to sign an Inventor's Declaration and an Assignment, which evidences the inventor's assignment to Penn of the inventions claimed and any patent(s) that issue. Patent applications may be filed in the United States and/or in other countries,

and the required paperwork may differ. PCI will keep you informed regarding in which jurisdictions patent applications are filed.

Is there such a thing as a provisional patent?

No. However, there is a provisional patent application, which is described below.

What is a provisional patent application?

Since a patent may only be issued to the first inventor to file an application, it is important to secure an early filing date prior to public disclosure. A provisional patent application is a type of patent application that secures a filing date for the application, and reserves the applicant's right to file a later, more detailed non-provisional application, without negatively impacting the length of the patent term if a patent ultimately issues. A provisional application automatically expires after 12 months.

WHAT IS THE DIFFERENCE BETWEEN A PROVISIONAL PATENT APPLICATION AND A REGULAR (OR "UTILITY") PATENT APPLICATION?

U.S. provisional patent applications can provide a valuable tool for preserving patent rights while allowing for further development and refinement of the claimed invention. This useful feature of provisional patent applications occurs because the application preserves an inventor's priority filing date, but the provisional patent application is not examined during the year in which it is pending. A regular non-provisional application must be filed within one year of the provisional filing, in order to receive benefit from its earlier filing date. However, an applicant only receives the benefit of the earlier filing date for material that is adequately described and enabled in the original provisional application.

What's different about foreign patent protection?

Foreign patent protection is subject to the laws of each country, although in a general sense the process works much the same as it does in the United States. In most foreign countries, however, an inventor will lose any patent rights if the invention is publicly disclosed prior to filing the patent application. In contrast, the United States has a one-year grace period which may allow for some protection of patent rights for publicly disclosed inventions.

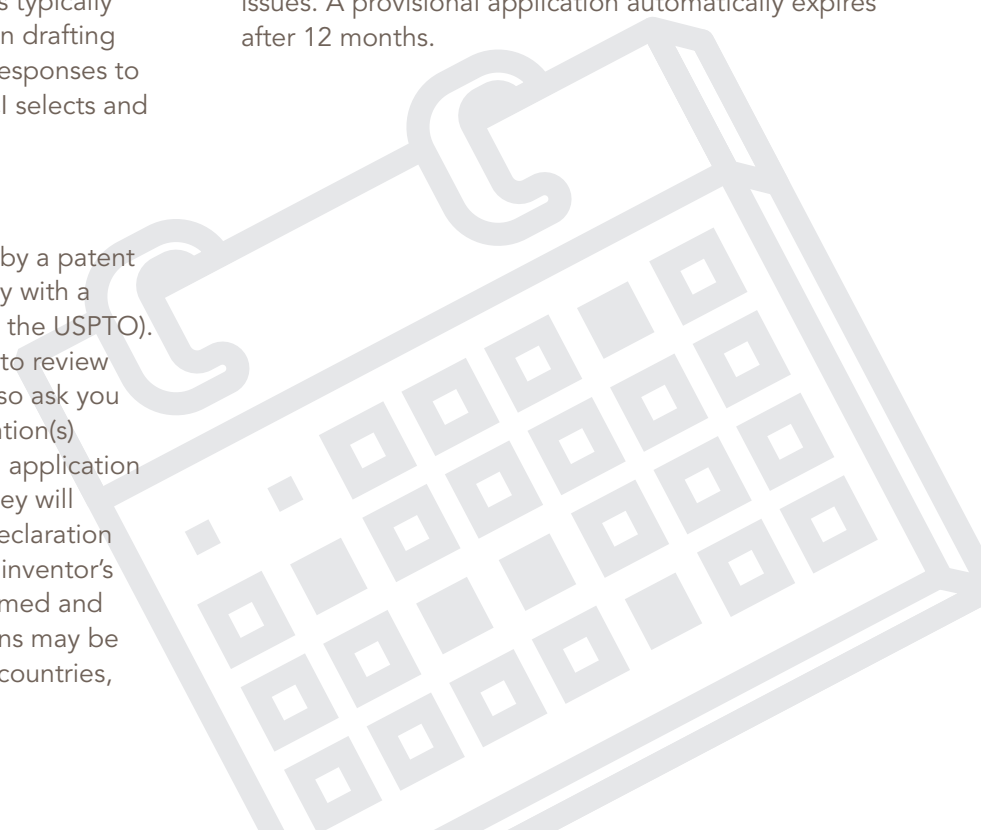
Is there such a thing as an international patent?

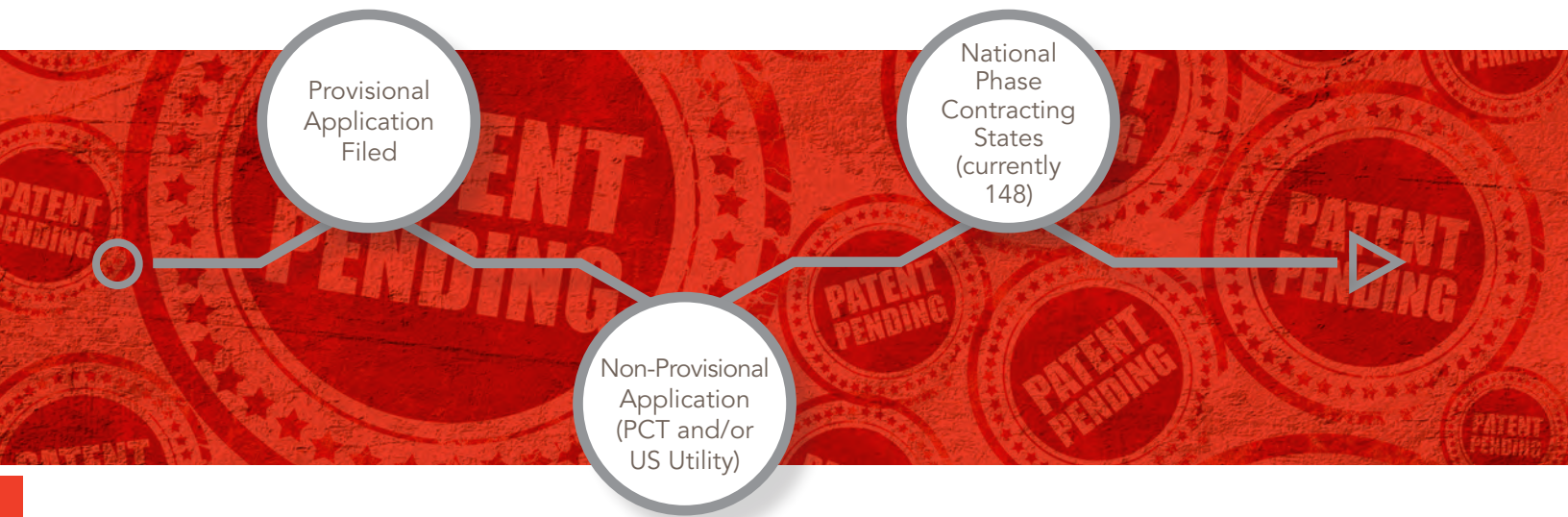
Although an international patent does not exist, an international agreement known as the Patent Cooperation Treaty (PCT) provides a streamlined filing procedure for most industrialized nations. A PCT application preserves the applicant's right to file in domestic and certain foreign jurisdictions. For U.S. applicants, a PCT application is generally filed one year after the corresponding U.S. application (either provisional or regular) has been submitted. Eighteen

months after the PCT is filed (30 months after the provisional is filed), the application must be filed in the national patent office of any country in which the applicant wishes to seek patent protection.

The PCT provides two main advantages. First, it delays the need to file costly foreign applications until the 30-month date, generally providing the applicant with ample opportunity to further develop, evaluate, and/or market the invention for licensing. Second, the international preliminary examination often allows an applicant to get early feedback about patentability of the invention.

An important international treaty called the Paris Convention permits a patent application filed in a second country (or a PCT application) to claim the benefit of the filing date of an application filed in a first country. However, pursuant to this treaty, these so-called "convention applications" must be filed in foreign countries (or as a PCT) within one year of the first filing date of the U.S. application





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

Currently, the average utility patent application remains pending for about two years, although inventors in the biotech and computer fields should plan on a longer waiting period. If the utility application is filed in the U.S., depending on the type of technology, the patent attorney will receive written notice in about 1-2 years or longer from the USPTO as to whether the application and its claims have been accepted in the form as filed.

More often than not, the USPTO rejects the initial application because either certain formalities need to be corrected, or the claims are not patentable over the “prior art” (anything that scientists in the field have made or publicly disclosed in the past). 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 explain why the USPTO’s position is incorrect. This procedure is referred to as patent prosecution.

Often it may take up to two USPTO Official Actions and two responses by the patent attorney—and sometimes 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. During this process, input from the inventor(s) is often needed to confirm the patent attorney’s understanding of the technical aspects of the invention and/or the prior art cited against the application.

Patent applications are kept confidential for a period of time, but then are published, typically 18 months after the first provisional is filed. After an application is published, the full application and information about prosecution can be found on the patent office website (www.uspto.gov).

Once a U.S. patent is issued, in general, it is enforceable in the United States for 20 years from the initial filing of the non-provisional application or PCT application, assuming that USPTO-mandated maintenance fees are paid during that 20-year period. (There are some exceptions to this general statement, particularly involving inventions in the pharmaceutical fields; contact PCI for more specific information about your invention and/or patent.)

Can a provisional patent application, regular utility patent application, or PCT application be enforced or used to exclude others from practicing my invention?

No. Only a validly issued patent can be enforced or used to exclude others from practicing the claimed invention. Patent applications cannot be enforced.

Why does PCI protect some intellectual property through patenting?

Patent protection is usually highly desirable for a potential commercialization partner (licensee) because it can protect the commercial partner’s often sizable investment required to bring the technology to market. However, not all inventions are patentable or justify the significant time, expense, and effort required to seek patent protection. PCI carefully reviews both the patentability and commercial potential of an invention before investing in the patent process.

Who decides what gets protected?

PCI and the inventor(s) will often jointly consider relevant factors necessary to make decisions relating to the potential filing of a patent application. If your invention was made using sponsored research funds, PCI may also consult with the funder(s). Ultimately, however, PCI makes the final decision as to whether

to file a patent application, seek another form of legal protection, or decline to pursue through PCI.

What is the cost of obtaining a patent?

Filing and prosecuting a regular U.S. patent application through to issuance can cost between \$15,000 and \$30,000, on average. Filing applications and obtaining issued patents in other countries may cost \$30,000 or more per country per application, on average. Also, once a patent is issued in the United States or in foreign countries, certain maintenance fees are required to be paid every few years, to keep the patent valid and enforceable.

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 PCI licensing associate will need to review that 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 University of Pennsylvania will usually enter into an Inter-Institutional Agreement that designates one of the institutions to take the lead in protecting and licensing the invention, and provides for sharing of expenses associated with the patenting process and allocating licensing revenues.

If the technology is jointly owned with a company or foundation, or in some cases if a company or foundation funded the University research but did not participate in the research which led to the invention, the licensing associate will consult with the company or foundation to determine the appropriate patenting and licensing strategy.

Will the University initiate or continue patenting activity without an identified licensee?

On the basis of its evaluation, the University may elect to accept the risk of filing and protecting a patent application without an identified licensee. After University rights have been licensed to a licensee, the licensee generally pays the patenting expenses that have been incurred up until the time of license (historical costs) and any patent expenses from the time of license forward (ongoing expenses).

The University sometimes decides to cease further patent prosecution and expense after a reasonable period of attempting to identify a licensee has transpired or if it is determined that it is not possible to obtain commercially valuable issued claims from the USPTO.

TANGIBLE RESEARCH MATERIALS

What are tangible research materials?

Tangible research property is defined more fully in the Penn Patent Policy, but in general, tangible research property or materials describe unique materials that are owned by and typically created at Penn.

Most often, tangible research property or materials refers to biological materials such as specialized or unique reagents, cell lines, plasmids, and vectors, but can also pertain to chemical compounds. Tangible research property may, or may not, be eligible to be protected by a U.S. patent.

KNOW-HOW

What is know-how?

Know-how is distinct from patents, copyright, and trademarks because it generally refers to the technical knowledge and skill required to perform a task. It can also refer to nonpublished data, information, protocols, techniques, methods, processes, procedures, trade secrets, chemical structures, and sequences or other types of knowledge. Know-how often resides with certain faculty members or other individuals and thus can sometimes be difficult to transfer to third parties and even harder to protect. In some cases, the know-how can be identified and/or reduced to writing, such as when it refers to protocols or certain data.

WHAT IS A COPYRIGHT AND HOW IS IT USEFUL?

A copyright is an intangible property right that can arise in an original work of authorship that is fixed in a "tangible means of expression". Common forms of "tangible means of expression" include books or other written media, and videos. Copyright protection attaches at the moment the original work of authorship is fixed in a tangible means of expression, whether the work is published or unpublished. Copyright can protect the way in which an idea is expressed, but not the idea itself. Similarly, for a computer program, the copyright may cover the source and object code, but not the processes that the code causes a machine to perform.

Owning a copyright for an original work can be a valuable right, as in general only the owner of a copyright or an individual with the owner's permission can make copies of the work and distribute the work publicly through print or electronic media. For performing arts and visual art, in general only the copyright owner or someone with permission can publicly display or publicly perform the work.

A U.S. copyright lasts for a long time. For many works created in the U.S. after January 1, 1978, the copyright is in effect for the author's life plus 70 years.

COPYRIGHT

What is a derivative work as it relates to copyrights?

A copyright owner is also the only person in most circumstances who can prepare or give permission for the creation of a "derivative work". A "derivative work" is an original work of authorship based on the material protected by the original copyright, which expands, abridges or makes other copyrightable modifications to the original work. Some common examples of a derivative work include: a French language translation of an English language novel or poem; a movie screenplay

based upon the original mystery novel, or if computer code is involved, the rewriting of the code in a different computer language.

If the copyright owner grants permission to prepare a "derivative work", only the new original material can be the subject of a new copyright and the original owner retains the copyright in the preexisting work.

Who owns a copyrightable work created during employment or study at the University of Pennsylvania?

Penn’s policy on ownership of copyrights for works created by faculty can be found in Section III.D. of the Faculty Handbook³ (<http://bit.ly/pennfacultyhandbook>).

In general, Penn follows the academic custom that ownership of the copyright for faculty-created books, articles, and presentations resulting from scholarly research, teaching, and writing resides with the faculty member creating the work. Faculty generally have the individual right to own and enforce copyright in their work, and to transfer or publish the work for profit. This policy also includes computer software and certain types of courseware, although Penn retains a royalty-free permanent license to use the software and courseware for reasonable academic purposes.

Penn also has adopted Open Access Guidelines which encourage faculty to retain certain of their copyright rights to allow open publication of their scholarly works, when contracting for publication in a journal or with a publisher. You can review the Open Access Guidelines here: <http://bit.ly/openaccessguidelines>

However, there are three main exceptions to the general rule that the faculty member (rather than Penn) owns the copyright in a creative work resulting from their research, teaching, or scholarship. Where one of these exceptions applies, Penn owns the rights and title to the copyright.

The exceptions are listed in the Faculty Copyright Policy, but in general and as a summary, the three main exceptions are:

1. If the work is produced using government or sponsored research funds where Penn has a contractual obligation regarding any copyrightable work resulting from the sponsored work, **or**

2. If the original work is determined to be a “work made for hire” as defined in the Faculty Copyright Policy. Under the policy, a “work made for hire” is an original work that is prepared based on the express direction of a supervisor, prepared as part of specific job duties in a Penn job description, or prepared as part of Penn administrative duties. Works prepared by faculty as part of instructional or research activities are not considered “works made for hire” for purposes of the Faculty Copyright Policy⁴, **or**

3. If the creation of the original work requires the substantial use of University resources or non-faculty Penn employees (unless there is a prior agreement to the contrary). In some circumstances, a faculty member voluntarily may want to assign their copyright rights to Penn, to enable Penn to commercialize the copyrighted work(s) using PCI’s resources and in return for the economic benefits available to the faculty member under the Faculty Copyright Policy.

If Penn owns the copyright under one of the three exceptions or if a faculty member voluntarily transfers copyright ownership to Penn, and then if PCI negotiates a business deal to commercialize the copyrightable work then the faculty author will receive a share of net revenues realized by Penn as set forth in the Faculty Copyright Policy. Finally, in addition to these exceptions there are situations that fall outside the Faculty Copyright Policy where, for example, the faculty member and Penn enter into a customized written agreement for a project that requires the faculty member to provide services beyond their normal duties. In such cases, the written agreement will govern the allocation of rights in copyrightable works created in the project and the financial arrangements.

For non-faculty employees of Penn, the copyrights in works they create in the scope of their employment (e.g., written materials, photos, software, videos) belong to Penn under the “work made for hire” provisions of the Federal Copyright Act. As the owner of such works, Penn can exercise all rights of the copyright owner without the permission of or additional compensation to the employee.

In general, students own the copyright to the academic works they create, such as their papers, projects, theses, and dissertations. However, under Penn’s policies or conditions applicable to specific courses, or the contracts funding the student’s research or studies, Penn may have certain rights with respect to student copyrightable works, such as the right to distribute copies of dissertations through Penn’s Scholarly Commons.

How do I represent a proper copyright notice?

Legally, works that are eligible for copyright are protected as soon as they are fixed in a tangible medium, e.g., written on paper or saved as a computer file. Thus, whether or not a formal copyright application is filed or a copyright notice is included, copyright protection often exists automatically. Nonetheless, PCI recommends that authors include a copyright notice with the original work. Depending on how the original work is presented, the notice may be 1) written on the publication; 2) included on the website; 3) added as a text graphic on a video; 4) added as a statement on an audio file; or 5) included in the program for a performance of the work.

If the copyright is owned by Penn, this notice should be used:

© [insert current year] The Trustees of the University of Pennsylvania. All rights reserved.

A similar notice can be used for an individually owned copyright, substituting the author’s name for that of the Trustees. It is advisable to include the author’s contact information with the copyright notice to make it easier for individuals wanting to use the copyrighted materials to request permission.

A copyright may also be registered with the U.S. Copyright Office at any time during the life of the copyright. However, registration is not required and is important primarily if a copyright owner wants to enforce copyright against someone allegedly infringing their copyright.

³ “Policy Relating to Copyrights and Commitment of Effort for Faculty” (the “Faculty Copyright Policy”)

⁴ Penn’s Faculty Copyright Policy defines “work made for hire” for faculty more narrowly than the Federal Copyright Act. The Federal definition of “work made for hire” applies to all works created by an employee within the scope of their employment, and certain other works specified in the federal law.

How can I learn more about University of Pennsylvania copyright policies?

Faculty may consult Penn’s “Policy Relating to Copyrights and Commitment of Effort for Faculty” which is Policy III.D in the Penn Faculty Handbook. However, there often may be complex and/or fact-specific issues that may arise involving copyright and interpretation of the Faculty Copyright Policy. If an author believes an original work has potential commercial value either through use by or sale to others, PCI can assist in evaluating the work and advising on Penn’s interest in commercialization and best options. An author can contact PCI to discuss the work and copyright and licensing. In addition, the Office of General Counsel has attorneys who have expertise in copyright law and Penn policies on working with faculty on copyright issues. Faculty are welcome to contact them for legal advice.

For software and computer code, options include publication, allowing academic use, making them available as open source or in the public domain, or commercialization through PCI.

For more general information about copyright, please see:

Penn Libraries websites: <http://guides.library.upenn.edu/copyright>

U.S. Copyright Office: <http://copyright.gov/title17/>

TRADEMARK

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

A trademark is a unique word, name, symbol, device, or combination that is used in commerce to identify and distinguish the goods or services of one manufacturer or seller from those manufactured or sold by others, and also to indicate the source of the goods or services. A trademark applied to services is often called a service mark. In short, a trademark is a brand name and the value of a trademark rests in its brand recognition, also called “goodwill”. Depending on the strength of the goodwill in a trademark, the owner can prevent others from using the same or a confusingly similar mark on similar goods or services. Rights to use and prevent others from using a trademark are a valuable business asset. Unlike a patent or copyright, a trademark generally can last indefinitely, as long as there is goodwill in the mark, and the mark has not been abandoned.

What is trademark registration?

In the United States, a trademark may be registered at the state and/or federal level, after the claimed owner files an application. At the federal level, trademark registration is a procedure in which the United States Patent and Trademark Office (USPTO) examines the filed application, and determines whether the applicant has a right to use a trademark and to exclude others from using the same or a confusingly similar mark for the same or similar goods or services.

Trademarks generally become protectable once they are adopted and used in commerce to identify specific goods or services, and begin to build goodwill, all of which can occur before one files an application or receives an issued trademark 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. 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. However, it is not necessary to register a trademark or service mark to build rights in a trademark or to prevent others from infringing upon the trademark. Similar to patents and copyrights, trademark rights may ultimately need to be enforced through litigation. Once you adopt a name, logo, or symbol as a trademark and use it in commerce to identify goods or services, you may place the “TM” symbol after the trademark. However, it is a federal crime to use the ® symbol unless and until you receive an issued federal trademark registration.





*"Diligence is the mother of good luck."
— Benjamin Franklin*



COMMERCIALIZATION

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PCI has created a clear and consistent commercialization process to facilitate innovation by faculty at Penn from the idea stage through to a final agreement and business relationship.

Along the way, PCI's staff works closely with faculty members to market and protect their intellectual property. PCI also offers many programs, tools, services, and educational events designed to complement the commercialization process, all of which can be found on PCI's website.

What is a faculty member's role during commercialization?

The role of a faculty member can vary depending on need, interest, and involvement; the interest of the licensee in utilizing faculty services for various assignments; and any contractual obligations related to the license or personal agreements. Examples of continuing faculty involvement include sponsored research or joint development collaboration activities with licensees, scientific advisory and/or consulting relationships, or joint venture formation activities.

HOW DOES PCI COMMERCIALIZE FACULTY INVENTIONS?



INVENTION

Research paths to an invention can be supported by Penn, government grants, and corporate partnerships



DISCLOSURE

An inventor uses Inventor Portal to disclose, so PCI can protect the invention and create a plan for commercialization



PROGRAMS & ASSESSMENT

An assigned Technology Licensing Officer assesses commercial value and begins marketing efforts to industry partners



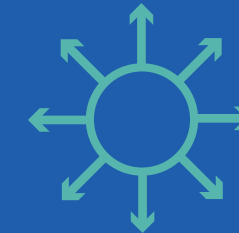
PROTECTION

Disclosures with commercial potential are protected through various channels (patents, copyright, trademarks, trade secrets, and/or know-how)



COMMERCIALIZATION

PCI and the inventor determine the best commercialization strategy, which may include licensing to industry, starting a company via PCI Ventures, or pursuing a corporate partnership via Corporate Alliances



MARKETING

PCI conducts a market analysis to identify potential clients and partners, creates marketing collateral, and lists the technology on our website. PCI may also market through programs and events, print and web media, and partnerships



BUSINESS RELATIONSHIPS

PCI works to generate agreements or relationships that may include an option and/or license to the technology, an MTA or SRA, or a new venture project

What revenues are generated for the University through commercialization?

Most licenses have initial or intermediate licensing fees that are relatively modest until a product is ready for sale on the open market (especially for relatively cash-strapped startups) but on rare occasion can reach hundreds of thousands or even millions of dollars. Royalties on the eventual sales of the licensed products can in some circumstances generate significant recurring revenues, although it usually takes many years to occur, if at all. Equity, if included in a license, can also yield long term returns on occasion, but only if a successful equity liquidation event (public equity offering or a sale of the company, etc.) occurs. A recent study of licenses at U.S. universities demonstrated that less than 1 percent of all licenses yield over \$1 million back to the university to share with the inventor(s) over their entire lifespan.

Despite these relatively long financial odds, it is important to bear in mind that although most licenses do not yield substantial revenues, almost all of them involve the productive connection between the creator of a technology and a commercial development partner that often further advances the value of the discovery or benefits society. Thus, the rewards of an invention being further

developed and potentially reaching the market are often more significant than the financial considerations.

What will happen to an invention if the startup company or licensee is unsuccessful in commercializing the technology? Can the invention be licensed to another entity?

Licenses, particularly exclusive ones, typically include performance milestones that, if unmet, may result in the termination of the license and return of the technology to Penn. This termination sometimes

allows for subsequent licensing to another business. Licensees may also choose to sublicense all or a portion of their rights to another company to aid in the commercialization and development of the technology that go beyond the original licensee’s capabilities and interests.



MARKETING

PCI staff use many complementary resources and strategies to identify potential licensees and to market inventions in collaboration with Penn inventors. Often the existing relationships of the inventors, PCI staff, and other researchers are useful in marketing an invention. Market research can also assist in identifying prospective licensees/marketing targets.

To publicize inventions, PCI leverages conferences and industry events, actively presents available technologies and business opportunities on our website and in our various newsletters and publications, and makes regular direct contact with industry. Faculty publications and presentations are often excellent marketing tools as well.

How are most licensees found?

The most likely potential licensees for a given technology are often already known to the inventors. Thus, research and consulting relationships and close communication and collaboration between PCI and inventors are often the most valuable source for potential licenses. Licensees are also identified through existing relationships and active marketing outreach of PCI staff. We attempt to broaden these relationships through contacts obtained from website posting inquiries, market research, industry events, and further cultivation of existing licensing relationships.

How long does it take to find a potential licensee?

Although for some technologies potential licensees are immediately evident and interested, it can take months and sometimes years to find a licensee for other technologies. When locating a potential licensee, important factors to be considered include the novelty and impact of the invention (sometimes referred to as its “disruptive potential”), its stage of development, competing technologies, and the size and intensity

of the market. Most university inventions tend to be at an early stage of development and thus require substantial development and commercialization investments, which can make it challenging to attract and secure an immediate licensee.

What activities occur after technology is licensed?

Most licensees continue to develop an invention to enhance the technology, reduce risk, demonstrate (or validate) reliability, and satisfy the market requirements for adoption by customers. This process can involve additional testing such as:

- prototyping for manufacturability, durability, and integrity;
- clinical trials for safety, toxicity, and efficacy; and
- further refinement to improve performance and other characteristics.

Documentation for training, installation, and marketing is often created during this phase along with benchmarking efforts to demonstrate the product/service advantages (i.e., societal benefit) and to position the product in the market.

Can there be more than one licensee?

Yes. An invention 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.

How is the decision made as to whether to commercialize software with a traditional or an “open source” license?

Generally, PCI supports Penn software developers who choose to make their programs available to the public through open-source mechanisms, provided that open sourcing is consistent with any obligations to sponsors and funders.

LICENSING

What are the PCI Licensing Groups?

The PCI Licensing Groups are composed of business development professionals who work directly with Penn inventors and private sector companies to actively license Penn technologies and to facilitate other types of contractual commercial relationships.

Working with the PCI Licensing Groups

PCI has technology licensing officers (TLOs) and defined Licensing Groups situated in strategic locations around campus, including fully-staffed satellite offices in the Perelman School of Medicine and the School of Engineering and Applied Sciences, to serve the interests of the Penn faculty and staff. To find a TLO in the appropriate Licensing Group, please visit <http://www.pci.upenn.edu/who-we-are/>.

CORPORATE CONTRACTS

What are Corporate Contracts?

Corporate contracts are research agreements that facilitate a variety of important activities and agreements between Penn researchers and private sector companies such as industrially sponsored research activities; R&D collaborations; or access to proprietary research materials, information, or know-how.

Working with the PCI Corporate Contracts Group

PCI has a dedicated team of Corporate Contract negotiators to serve the interests of Penn researchers. To connect with one of our Corporate Contracts negotiators, please visit <http://www.pci.upenn.edu/who-we-are/>.

CORPORATE OUTREACH

What is corporate outreach?

Corporate outreach is a defined process whereby PCI takes the lead in actively facilitating connections between Penn researchers and inventors with potential development and commercialization partners in the private sector.

How does PCI provide Corporate Outreach services?

PCI’s Corporate Outreach Group works proactively with faculty inventors to build and develop relationships that can help advance mutually beneficial research goals. Relationships can take many forms at Penn, and can include features such as licenses, sponsored research, corporate alliances, or even spin-outs. PCI has extensive experience developing each of these types of commercial relationships at all levels of technology development and throughout many different industrial sectors.

Working with the PCI Corporate Outreach Group

Do you think your research can benefit from a relationship with private industry? Are you looking to explore a new relationship or expand an old one? PCI’s Corporate Outreach Group will work closely with you to connect with potentially interested parties in the private sector to discuss the establishment of relationships that can help you further advance your R&D goals.

If you would like to explore the creation or expansion of a corporate relationship, contact PCI’s Corporate Outreach Division at any time at <http://www.pci.upenn.edu/who-we-are/>.

CORPORATE ALLIANCES

What are Corporate Alliances?

Corporate alliances are typically multi-year, multi-million dollar research and development collaborations designed to dramatically accelerate the translation of Penn’s cutting-edge technologies to the marketplace and to bring benefit to patients with unmet needs. Corporate alliances often blend a combination of licenses to Penn-owned intellectual property, and significant industrial sponsored research arrangements as well as contractual agreements allowing facilitated access to research resources, materials, information, and know-how.

Working with Corporate Alliances

The Corporate Alliances group at PCI is a fully-capable, cross-functional team comprising business development, scientific, legal, and contract management expertise that can help you establish a new corporate alliance or assist you in interfacing with an existing alliance at Penn. To connect with one of our Corporate Alliances team members, please visit <http://www.pci.upenn.edu/who-we-are/>.

STARTUPS


What are startups?

Startups are spin-out companies based around technology developed and licensed from Penn. Penn inventors and researchers may elect to form companies on their own or with direct support from Penn. PCI has assembled a robust and experienced PCI Ventures team to support new company creation. PCI Ventures offers a wide range of new business creation and support services.

To connect with the PCI Ventures team, please visit <http://www.pci.upenn.edu/pciventures/>



*"Who is wise? He that learns from every one."
— Benjamin Franklin*



COMMERCIAL AGREEMENTS AND CONTRACTS

OPTIONS, TERM SHEETS, MOUS / LETTERS OF INTENT

What is an Option?

Option Agreements, or Option Clauses within research agreements, describe the conditions under which the University grants a right for a limited period of time for the option holder to negotiate a license for Penn-owned intellectual property. Option Clauses are often provided in a sponsored research agreement to corporate research sponsors so that the corporate sponsor obtains an exclusive, contractual, first right to

negotiate a license to any intellectual property that is discovered in the course of funded sponsored research.

Option Agreements are also entered into with third parties who wish to evaluate a technology prior to finalizing a full license agreement while also preserving their opportunity to negotiate an exclusive or non-exclusive license from Penn during the period of the Option. An Option Agreement does not generally allow a company to use the technology in any commercial manner.

What is a Term sheet?

A term sheet is typically a non-binding understanding between the university and a potential licensee, setting forth the basic terms and conditions under which a Penn technology could be licensed to an outside party. A term sheet often serves as the initial basis upon which a more detailed legal document, such as a patent license agreement, will be drafted with the help of the legal team. A term sheet lays the groundwork for ensuring that the parties involved in the business transaction are in general agreement on most major aspects of the deal, especially financials, thereby avoiding misunderstandings during future negotiations.

What is an MOU/Letter of Intent?

Similar to a term sheet, a memorandum of understanding ("MOU"), sometimes referred to as a Letter of Intent, is a non-binding agreement setting forth the basic terms and conditions under which Penn

may establish more formal contractual relationships with outside parties. An MOU typically defines how intellectual property will be shared and the relative roles and responsibilities of the involved parties. MOUs are often favored over term sheets when the business arrangement is a less structured collaboration rather than a straight-forward license agreement.

LICENSES

What kinds of things can be licensed?

Generally, licenses include a grant of rights to a form of intellectual property such as an issued patent or pending patent application, a copyright, a piece of software, a device prototype, a tangible research material or reagent, a defined data set, etc.

Can know-how be licensed?

Because know-how often exists in the individual's mind and skillset, Penn will generally try to avoid licensing know-how and if licensed, licensing of know-how is typically done solely on a non-exclusive basis and only where it can be reduced to a tangible form. Exclusive licensing of know-how is generally prohibited as it typically conflicts with Penn's mission of broadly disseminating knowledge and skill for the benefit of society, and negatively impacts our faculty's ability to conduct future research that might require use of that know-how.

How is a company chosen to be a licensee?

A licensee is chosen by PCI in consultation with the inventors, 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 startup company is a better option.



WHAT IS A LICENSE AGREEMENT?

License agreements describe the rights and responsibilities related to the use and exploitation of intellectual property developed at Penn by the party obtaining the license. University license agreements usually stipulate that the licensee should diligently seek to put the intellectual property to commercial use for the public good and provide a reasonable return to Penn. License agreements can be exclusive, meaning that only that licensee has rights to exploit a particular technology in the licensed field, or non-exclusive, meaning that more than one licensee can obtain a license to the same intellectual property in the same field of use.

WHAT CAN I EXPECT TO GAIN IF AN INVENTION I MADE IS LICENSED?

Most inventors enjoy the satisfaction of knowing their inventions are being developed for the benefit of the general public. New and enhanced relationships with businesses are another outcome that can augment one's teaching, research, and consulting activities. In some cases, additional sponsored research funding and support may result from the licensee.

Additionally, as required by the Bayh-Dole Act and per University policy, a significant portion of any net income from a patent license is shared with the inventor(s). For additional information on how licensing income is distributed, please see the University's Patent and Tangible Research Property Policies and Procedures (<http://bit.ly/patentandTRP>).

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

Many licensees request, and sometimes require, the active assistance of the inventor to facilitate their commercialization efforts, at least in the early stages of development. This assistance can range from infrequent, informal interactions to a more formal collaboration. Working with a new business startup in contrast to working with an established company can, and often does, require substantially more time, depending on your role in or with the company and your continuing role within the University. Under all circumstances, your participation with a startup or well-established company is governed by University conflict-of-interest policies.

TRM (TANGIBLE RESEARCH MATERIALS) LICENSE AGREEMENT

When do I need a TRM License Agreement?

A TRM (Tangible Research Materials) License Agreement is required when you want to share tangible research property (as defined in the Penn Patent Policy) with a commercial party. (By contrast, if you wish to share tangible research property with another university or non-profit organization for non-commercial purposes, you should instead request a Material Transfer Agreement [MTA]). A TRM License agreement allows a commercial party, usually for a fee, to use the licensed materials for a limited and defined research project, or commercial distribution purposes, on a non-exclusive basis and for a limited period of time. If a company would like to use tangible research materials for broader commercial purposes, the company generally must enter into a License Agreement with the University.

How do I get a TRM?

If you are approached by a company who wants you to transfer or license tangible research materials to the company, please contact your usual Technology Licensing Officer. If you do not know who to contact, please email pciinfo@pci.upenn.edu. If you want to license tangible research materials from someone else, such as another university, ask your business administrator to request an incoming material transfer agreement.

CONFIDENTIAL DISCLOSURE AGREEMENT (CDA) OR NON-DISCLOSURE AGREEMENT (NDA)

What is a CDA (Confidential Disclosure Agreement)?

A CDA (or NDA, the two terms are used interchangeably and almost always have very similar terms) is a binding, legal agreement between two or more parties (e.g. sometimes Penn and a third party, sometimes you individually and a third party) that defines confidential information, allows the parties to exchange confidential information, defines what each party can do with the other party's confidential information (e.g. not share it with others that are not already bound to the same terms of confidentiality), and defines the purpose of the proposed sharing of information between the parties. In general, the purpose of a CDA is to protect discussions prior to a planned follow-on action by the parties, such as a research collaboration or license. Importantly, CDAs can protect the patentability of any proprietary information, patents, patent applications, data, or know-how that has not yet been published. Without this type of protection, valuable intellectual property rights may be irretrievably lost.

When would I need a CDA?

Any time that you know or suspect that you will be discussing unpublished data, information, or know-how with a third party for any reason, a CDA is advisable. When first discussing a relationship with a third party, a non-confidential discussion is strongly suggested to allow the parties to have a better understanding of the proposed transaction and to ascertain whether there is sincere interest in conducting a more in depth discussion. As just two examples, CDAs are used when you want to receive or share a nonpublic research

protocol before deciding whether to serve as a site in a clinical trial; or when you want to share unpublished research with a potential sponsored research funder, so the potential funder can learn more about your current research interests.

SPONSORED RESEARCH AGREEMENTS (SRAS)

What are SRAs?

Sponsored Research Agreements (SRAs) are contracts that establish the terms and conditions under which the University accepts funding to support the conduct of defined research projects. SRAs governing research projects between the University and a corporate, for-profit sponsor are administered by the Corporate Contracts group at PCI.

Who manages SRAs?

SRAs governing research projects between the University and non-profit organizations such as the government, National Institutes of Health (NIH), and foundations are administered by the Office of Research Services (www.upenn.edu/researchservices/). In addition, SRAs requiring an informed consent from study subjects (such as human clinical trials) are handled by the University's Clinical Trials Contracting Unit in the Office of Clinical Research of the Perelman School of Medicine (www.med.upenn.edu/ocr/). The Corporate Contracts group at PCI does, however, handle industrially sponsored SRAs governing veterinary clinical trials.

COLLABORATIVE RESEARCH AGREEMENTS (CRAs)

What are Collaborative Research Agreements (CRAs)?

Collaborative Research Agreements (CRAs) are similar to SRAs but govern more varied collaborative research endeavors. A CRA would be appropriate, for example, where the project involves participation in the research by scientists from both the University and an outside party, or where an outside party is also providing materials for use in the research. Projects giving rise to a CRA may or may not involve funding from the outside party.

As with SRAs, PCI administers CRAs governing research projects between the University and a corporate, for-profit collaborator, excluding those CRAs which involve informed consent from study subjects (for example human clinical trials). The process for entering into a CRA is the same as an SRA.

MASTER RESEARCH AGREEMENTS

What are Master Research Agreements?

When a University Principal Investigator anticipates entering into multiple research projects with a single company over an extended period of time, PCI may advocate the use of a Master SRA or Master CRA. For a Master Agreement, the parties reach an initial agreement as to the generally relevant terms and conditions – such

as ownership of and the right to use research results and intellectual property generated from the research, publication rights, confidential treatment of information exchanged in connection with each project, and indemnification – as well as a form of Addendum to be executed for each new, specifically defined research project. The Addendum will typically include the details of the project, the project budget, project timeline, payment information, and any modifications to the terms and conditions of the Master Agreement applicable to that particular project. Having a Master Agreement is not appropriate for all situations, but when it can be employed it often can greatly expedite the agreement negotiation and execution process for any subsequent individual research projects.

DATA USE AGREEMENTS

What are Data Use Agreements?

If Penn wishes to obtain and use data from a company to facilitate research, or conversely a company wishes to utilize data from Penn, the parties will need to execute a Data Use Agreement. If you are requesting data from or want to send data to a for-profit entity, the Data Use Agreement will be handled by PCI. If you are requesting data from or want to send data to a not-for-profit entity (such as a foundation or another university), the data use agreement will be negotiated and signed by the Office for Research Services.

6 Industrial Equipment Evaluation Agreements generally fall under a Service Agreement request handled by the Corporate Contracts Group at PCI; however, Equipment Loan Agreements unrelated to research to be conducted are generally handled by Penn's Purchasing Services Group. If the loaned equipment will be used to conduct research on campus, please contact the Corporate Contracts Group at PCI initially.

7 <http://cms.business-services.upenn.edu/purchasing/>

8. Penn Purchasing Services also generally handles agreements where the University is interested in contracting for services to be performed by a third party company.

MATERIAL TRANSFER AGREEMENTS (MTAs)

What are MTAs?

In general, if the University or one of its researchers wishes to obtain research materials from a company to facilitate research, or conversely a company wishes to obtain research materials (other than tangible research property as defined in the Penn Patent Policy) from the University, the parties will need to execute a Material Transfer Agreement (MTA). Provided that the company is not a non-profit organization, and the material transfer at issue does not involve informed consent from study subjects (for example a human clinical trial), the MTA will be handled by PCI. MTA requests made by or to non-profit entities will be negotiated and signed by the Office of Research Services; MTAs involving materials for use in human subject research will be negotiated and signed by the Perelman School of Medicine's Office of Clinical Research contracting group.

SERVICE AGREEMENTS

What are Service Agreements?

As a non-profit academic research organization, Penn only utilizes service agreements in exceptional circumstances where the project is consistent with Penn's academic and research missions and where the project does not involve intellectual contributions by a Penn researcher. If a company wishes to contract with Penn to perform services on the company's behalf, the parties will need to execute a Service Agreement. If the company is a for-profit organization, the request to enter into a Service Agreement will be reviewed by PCI.^{6, 7, 8} If the request is from a non-profit entity, ORS will review the request.

AGREEMENT PROCESS

How are research agreements with for-profit companies processed and completed?

(Excluding clinical trial agreements or agreements including human subjects of research)

PLANNING

- Principal Investigator and scientific contact at company agree upon research protocol, time frame, budget*, payment schedule, etc.

SUBMISSION

- If funded by company: submit to Penn ERA
- If not funded by company: submit to Penn RIS
- Principal Investigator must disclose if they have significant financial interest. If so, submit a disclosure through FIDES. Please refer to the University's then-current policies regarding what constitutes a significant financial interest.

DEPARTMENTAL APPROVAL

- Departmental Chair and/or Dean of School will approve. (In some cases, additional approvals must be obtained, also.)
- Negotiator from PCI will be assigned

NEGOTIATION

- Negotiator confirms details of project with PI
- Negotiation begins, including intellectual property and ownership, publication rights, confidentiality, indemnification, and (if applicable), additional budget and payment information
- Negotiator's objective: to put an agreement in place that is consistent with Penn policies

AGREEMENT

- PCI finalizes the agreement and notifies Principal Investigator and ORS who help to administer the executed contracts

* inclusive of all direct and indirect research costs (indirect expenses are calculated in strict accordance with university policies and federally established rates)



*"Energy and persistence conquer all things."
— Benjamin Franklin*



PATENT POLICY

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Penn's Patent and Tangible Research Property Policies and Procedures

The University of Pennsylvania's current Patent and Tangible Research Property Policies and Procedures may be found on the PCI website at <http://bit.ly/patentandTRP>. This summary is intended to provide a more accessible and user-friendly guide to how Penn treats inventions created by faculty, staff, students, and other researchers in the course of their employment or research at Penn. Please note, however, that this summary and guide is presented for informational purposes only; the terms of the Patent Policy are subject to change, and, in the event of a conflict between a statement in this summary and guide, and the language in the Patent Policy itself, the language in the Patent Policy governs.

What is the Penn Policy on Inventions and Patents?

Inventions and the related intellectual property created by faculty, students, Penn employees, and visitors (e.g., visiting scientists or trainees) —1) in the course of employment at Penn; 2) resulting from work related to professional responsibilities at Penn; 3) from work done on University time; or 4) with substantial use of Penn resources from grants or otherwise—are the property of the University of Pennsylvania, not the individual inventor.

Penn has the right to be made aware of, own, and manage any inventions and associated intellectual property created under one of the four categories listed above or otherwise set forth in the Patent Policy.

What is a Participation Agreement?

As a condition of employment or the use of research facilities, Penn requires that a Participation Agreement be signed, which assigns all right and interest in these inventions and related intellectual property (including but not limited to patent applications and patents) to Penn. Under Penn's Patent Policy, even if the Participation Agreement has not been signed prior to the discovery of the invention, by accepting Penn employment, or using Penn resources to conduct any research, faculty, employees, and in some cases students (see below) are deemed to have automatically assigned their rights to any inventions. If you have not yet signed a Participation Agreement, please contact PCI.

What inventions aren't covered by Penn's Patent Policy?

Occasionally a faculty member, researcher, employee, or student may believe that an invention was not developed with Penn resources or support, or within the scope of their employment, and is not otherwise subject to the Patent Policy, and, therefore, may not be subject to ownership by Penn. If this occurs, the inventor must provide PCI with a written statement describing how the invention was developed and why they believe that it is not subject to the terms of the Penn Patent Policy. The Executive Director of PCI will then review the facts with members of the PCI team and either issue a written disclaimer of Penn interest in the invention, or decide that ownership of the invention should be held by Penn.

If an invention is not owned by Penn, the inventor may still request to use PCI's services and expertise in the assessment, protection, and commercialization of the invention. However, if Penn agrees to invest the significant time, effort, and expense required to manage the protection and commercialization of the invention it will generally require that the invention be

assigned to Penn and will treat the invention the same way as if it were an invention within the scope of the Patent Policy and initially owned by Penn.

What about Student Inventions?

Inventions made by students 1) in the course of employment at Penn; 2) resulting directly from work related to employment at Penn; 3) resulting from work under a grant or sponsorship requiring assignment to Penn; or 4) where the invention is co-created with another inventor who has a duty to assign the invention to Penn, will be considered the property of the University. Conversely, student inventions not falling under one of the categories above will remain the property of the student.

All inventions resulting from research done in Penn laboratories or facilities as part of a graduate or post-doctoral degree or non-degree program are the property of Penn.

Student inventors of inventions that are owned by Penn are considered "inventors" under the Patent Policy for purposes of sharing in distribution of revenues resulting from commercialization of inventions.

When do Return of Inventions occur?

Under certain circumstances, Penn may decide that it either does not want to pursue a patent application, wants to abandon a previously filed and pending patent application, or does not wish to continue to own and maintain an issued patent. Under these circumstances, the Patent Policy permits the inventor(s) to request that Penn return ownership of the invention to them. The procedure for returning an invention and intellectual property to the inventor is briefly summarized below and is often strongly influenced by whether there was federal or other outside sponsorship of the work leading to the invention.

If there is no federal or other outside sponsorship, PCI's Managing Director may decide to return the right in the invention and/or patent, subject to the terms and conditions in the Patent Policy. If there was federal or outside sponsorship of the work leading to the invention, Penn may need to comply with certain requirements of the sponsor or funding agency, such as obtaining the consent of the funding agency before transferring its rights to the inventor. In addition, any return would remain subject to any of the rights that are retained by the federal government or outside sponsor of the invention.

In all cases where Penn agrees to return an invention and/or patent, the inventor(s) must first sign a contractual agreement with Penn that includes at least all of these terms:

- If there is more than one inventor, each inventor receives an undivided interest in the whole invention.
- Penn reserves a royalty free, non-exclusive, and irrevocable right to practice the invention for educational, research, and clinical care purposes, and to permit other academic and not-for-profit institutions to do the same.
- Reimbursement to Penn for the costs already incurred for processing the invention or patent up to the time it is returned.
- Penn will receive 5% of all gross compensation from any further transfer or commercialization of the invention.
- The inventor has a plan for commercialization of the invention, and will report any future improvements made to the invention to allow PCI to determine ownership of those improvements.
- Rights are not automatically granted to improvements to the originally disclosed invention or new inventions created that relate directly or indirectly to the returned invention.

- No Penn personnel or resources can be used to protect or commercialize the invention after ownership is returned.

How are inventions owned by Penn licensed to others to use?

The mechanism for allowing commercial use of a Penn-owned invention by a company outside of Penn is a "license". If Penn grants a license, it will keep all ownership and title to the invention but will allow the commercial company to develop and sell products based on the invention.

PCI will generally keep the faculty inventor(s) informed during the marketing and license negotiation process, and consult and work with the faculty inventor during the negotiation process with the goal of making the best possible licensing decision for the inventor and Penn. However, the final decision as to whether and to whom an invention will be licensed, and the terms and financial arrangements of the license agreement, are ultimately determined by PCI and are not appealable.

How is equity allocated?

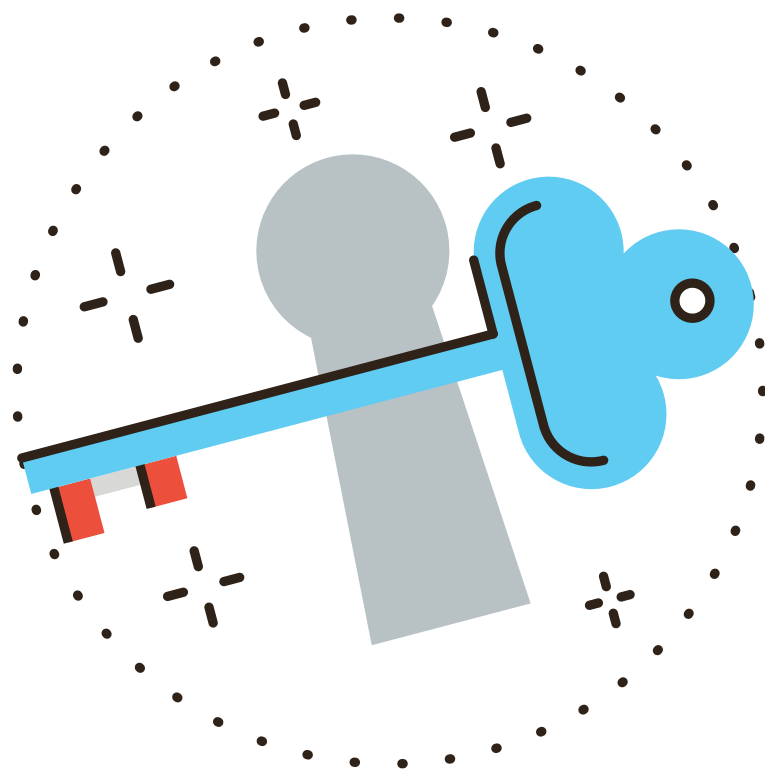
Under certain circumstances the type of invention or development risks involved in licensing an invention may result in Penn accepting equity ownership in the licensee as consideration for the grant of license to commercialize the invention. When Penn decides to accept equity as license consideration, the inventor(s) are entitled to receive 30% of this equity, provided that the inventor(s) are not also receiving their own individual equity share in the company outside of Penn's equity pool. Inventors who have their own independent equity stake in a licensee are generally obligated to waive their normal inventor distribution interest in the equity shares held by the university. The policies and structure of equity transactions can be complex, and inventors are highly encouraged to seek tax advice from their personal tax advisor.

PROTECTING ACADEMIC FREEDOM

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

Penn and PCI are strongly dedicated to protecting academic freedom and ensuring that faculty and researchers are able to freely publish and disseminate the fruits of their scholarship and research activities. However, since valuable patent rights may be affected or even destroyed by any public disclosure activities, it is best to submit an invention disclosure well in advance of communicating or disclosing your invention to people outside the Penn community. In addition, there are significant differences between the United States and other countries as to how early publication affects a potential patent and how damaging a public disclosure can be to invention patentability. Once publicly disclosed (published or presented in some form), an invention may have zero or at best minimal potential for patent protection outside of the United States. Within the United States prior disclosure within one year of patent filing does not necessarily eliminate patentability, but the ultimate value of a patent could be severely damaged, even within the United States, if it is not filed prior to any public disclosure.

Be sure to inform the PCI licensing associate assigned to you of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/thesis, publication, or other public presentation including the invention and they can help to ensure that it is protected in a timely manner that does not restrict your ability to publish or discuss your invention publicly in any way. PCI can also help to verify if any pre-publication review is required as a result of your sponsored research agreement and comply with any such requirement.



May I use tangible research materials created by others?

Yes, if the other party is willing to share materials and any terms of use conditions the provider may impose are acceptable to you and Penn. It is important to carefully document from whom and under what conditions you obtained materials so that we can help to determine if your use may impact the ownership rights of a subsequent invention or technology. In most cases, Penn requires the use of an incoming Material Transfer Agreement (MTA) for research materials being transferred into Penn. Information on submitting requests for materials may be found at <http://bit.ly/pennmtas>.

Will I be able to share tangible research materials created in my research with others?

Yes. Penn requires the use of an outgoing MTA or tangible research materials agreement (TRM) for the sharing of materials developed at Penn to any outside for profit or not-for-profit party. The Simple Letter Agreement or the Uniform Biological Material Transfer Agreement should be used when the outside not-for-profit institution is a signatory to the AUTM agreement. Sharing any materials with commercial colleagues or sharing human-derived materials with commercial or academic colleagues may require the use of additional terms and conditions. All requests for outgoing MTAs should be made through the Research Inventory System <http://bit.ly/rislogin>.

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

A sponsored research agreement should specify the intellectual property rights of the sponsor. Penn generally retains ownership of the patent rights and other intellectual property resulting from sponsored research, with the exception of certain types of clinical trial sponsorship agreements managed by the Office of Clinical Research at the Perelman School of Medicine. However, the sponsor may have a specified option to negotiate to obtain a license to the defined and expected outcomes of the research. Sponsored research contracts often allow the sponsor a limited time to negotiate for a license for any patent or intellectual property rights that may result from the research. Sponsors generally will not have contractual rights to discoveries that are clearly outside of the scope of the research. Therefore, it is important to carefully define the scope of work within a research agreement. Sponsored research projects funded by non-commercial sponsors, such as the federal government or not-for-profit foundations, are handled by the Office of Research Services (ORS). ORS project

representatives work closely with PCI on intellectual property issues that may arise in any sponsored research agreements that they manage.

What about publication of results created under sponsored research agreements?

The ability to freely publish research results is fundamental to Penn's mission as an academic research institution, and is zealously guarded by the negotiators at PCI and ORS. In a sponsored research or clinical trial agreement, the corporate sponsor may be afforded a short period of time to review a pending publication or disclosure to protect their own confidential information or to allow the protection of certain rights to intellectual property, but sponsors are never provided with rights to unduly delay or prevent publication.

What about Retained Rights?

Pursuant to the Bayh-Dole Act, Penn is required to retain certain research rights to continue to use licensed intellectual property where federal funding has been utilized in the development of such intellectual property, and to reserve rights – also known as march-in rights – for the federal government to exploit the IP under certain circumstances. In addition, it is Penn's policy to retain certain research rights in all of its licensed intellectual property, to enable further research and clinical care, even if no federal funding was used in the creation of the licensed intellectual property.

Furthermore, Penn generally retains the right to share its "retained rights" in such licensed intellectual property with other non-profit organizations and universities for non-commercial research purposes. This "retained right" may allow a researcher who leaves Penn for another university to continue research related to the invention at a new university, while the ownership rights in the original licensed invention remain at Penn.

CONFLICTS OF INTEREST

When do research-related conflicts of interest occur?

A conflict of interest may exist when financial or other personal considerations have the potential to compromise or bias professional judgment or objectivity regarding the design, conduct, or reporting of research.

Penn has a centrally published policy governing research-related *Financial Conflicts of Interest (FCOIs)*, the *University of Pennsylvania Policy on Conflicts of Interest Related to Research (the FCOI Policy)* at <http://bit.ly/fcoipolicy>. This policy is designed to identify and manage or eliminate financial conflicts related to specific research projects. Individual schools at Penn may have additional policies regarding research-related conflicts of interest. For example, for Perelman School of Medicine researchers, review the School research conflict of interest and extramural activity policies at <http://bit.ly/psomcoi> or through the Department of Faculty Affairs and Professional Development.

Below is a brief summary of the University's current FCOI in Research policy. You should refer to the actual policy for guidance. If there is a conflict or ambiguity between a statement in this summary and guide, and a term in the FCOI in Research policy, the term in the FCOI in Research policy will govern and take precedence.

The University's FCOI Policy applies to *Investigators* participating in research at Penn. An *Investigator* is any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research conducted under Penn's auspices. This policy applies regardless of whether the research is externally or internally funded.

A faculty inventor may not, under Penn's conflict of interest policies, hold a management or fiduciary position on a board of the company in which they hold equity or

to whom Penn has licensed intellectual property invented in part by that faculty member.

It is important that University inventors, whether faculty or staff, follow all Penn conflict of interest policies and disclose to their school dean and PCI if the inventor has a management role or financial interest in a company that is being considered as the licensee for their invention.

What are the investigator disclosure requirements?

Penn has specialized electronic disclosure sites depending upon your school affiliation where you must provide information about your significant financial interests, so a determination may be made whether there is a financial conflict of interest and whether it may be managed. You must disclose *Significant Financial Interests (SFIs)* (and those of your spouse or dependent children) that reasonably appear to be related to your field, discipline, or professional expertise. These are more specifically defined in the FCOI Policy but in general include: 1) any payments from a public company over the course of the past 12 months plus the value of any equity received from that company that, when aggregated, are greater than \$5,000; 2) payments over \$5,000 during the past 12 months from any non-publicly-traded company; 3) receipt of any amount of equity, regardless of value, in a non-publicly held company; 4) acceptance or performance of a management or officer role for any company; and 5) personal interests in certain types of intellectual property rights.

Disclosures generally must be updated at least annually, and anytime you submit a proposal to conduct sponsored research or a protocol for human subject research; anytime you are added as an Investigator on an ongoing research project; and within 30 days after you learn of a new SFI.

More information about where and how to disclose can be found at <http://bit.ly/coitraining>.

You may also need to consult the FCOI Policy of your own school regarding the scope of your extramural engagements in consulting arrangements with for-profit entities.

What are special disclosure considerations for investigator/inventors related to clinical trials?

If you have or acquire an interest in intellectual property that is being tested, evaluated, or developed in, or if its commercial value could be affected by, a clinical trial in which you plan to serve or currently are serving as an Investigator, you must first disclose that interest as a potential conflict of interest through the FIDES system. This requirement includes IP that is the subject of a copyright, issued patent, or a patent application (regardless of whether the IP has been licensed or is assigned to Penn).

What are special disclosure considerations related to startup companies?

If you are an owner or co-founder of a start-up company, you must disclose all equity in, payments from, or any fiduciary role for, that company before participating in any research that is sponsored by or conducted with the company or that could affect the company's interests.

What about FCOI determination?

Your disclosures of SFIs will be reviewed (as described immediately below) to determine if they could potentially directly and significantly affect the design, conduct, or reporting of the proposed research, thereby constituting a financial conflict of interest (FCOI). Disclosures are reviewed on behalf of the Vice Provost for Research, in most cases by the Conflict of Interest Standing Committee, which makes advisory recommendations to the Vice Provost. The Vice Provost for Research is responsible for making the ultimate determination regarding whether you have an FCOI and whether your

FCOI can be appropriately monitored and managed. Management conditions that may be imposed include disclosure in publications and presentations, to other researchers, and to human subjects, as well as certain types of restrictions on your role in the project. Other management or conflict reduction strategies may also be required.

When should investigators seek proactive guidance?

Penn's Research Integrity Office is directly responsible for administering Penn's Research-Related FCOI Program. Because a finding of an FCOI may have considerable implications related to your participation in research, you should contact the Research Integrity Office early in the process if you currently have, or anticipate that you may have, a financial relationship with a company that could affect or be affected by the conduct or outcome of your research. You should also feel free to seek additional guidance whenever a question or uncertainty arises. The Research Integrity Office can be reached at coi@exchange.upenn.edu. You may also find useful information at <http://bit.ly/coitraining>.

What other types of conflicts may require university, school, or departmental review?

There are potential conflicts of interest that are not addressed specifically by the FCOI Policy, but that nonetheless require assessment and may be subject to other policies, including policies that are specific to a particular school or program at Penn. Examples include, among others, the treatment and roles of students and trainees, supervision of individuals working at both Penn and a licensee company, use of space and equipment for company benefit, purchasing services or goods from the company, and conflict of commitment (i.e., your ability to meet your University obligations). Questions regarding these types of COI policies can generally be addressed to your chair or dean and/or the Research Integrity Office.

REVENUES

How are license revenues from patents, copyrights, and TRMs distributed?

License revenues from patents, patent applications, TRMs, and know-how are distributed according to the Patent Policy, and license revenues from copyright licenses are distributed according to the Faculty Copyright Policy. Revenues from license fees, royalties, and equity—less any unreimbursed patenting, licensing expenses, and certain types of other qualifying costs—are shared with inventors according to the distribution formula set forth in the applicable policy. Please refer to the Patent Policy and Faculty Copyright Policy for the specific terms regarding how revenues, expenses, and payments to inventors are calculated.

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

Under the Patent Policy, inventors who receive equity from a licensee directly, outside of the equity pool that Penn negotiates to receive, are generally required to waive their inventor's interest in their share of equity in the equity pool. Equity is defined under the Patent Policy as ownership interests or securities, including but not limited to shares of stock or securities; stock options; warrants or any other rights to purchase stock or securities; debt instruments; partnership interests in a general or limited partnership; or membership interests in a limited liability company or partnership. The Equity Pool is defined in the Patent Policy as "the total allotment of Equity negotiated by the University as consideration for a license of the University's interests in an Invention or Tangible Research Property."

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

Income distributed from license agreements to inventors are reported on Form 1099-Misc as Royalties. We strongly encourage you to consult your own tax adviser for specific advice and guidance.

CONSULTING

What about consulting?

Faculty members at Penn generally are permitted to engage in a limited amount of outside consulting activities within certain acceptable parameters that are defined in detail in the Penn Faculty Handbook. When researchers enter into consulting agreements, they are generally deemed to be acting outside of the scope of their employment. Therefore, consulting arrangements are not negotiated by Penn nor formally reviewed by PCI. Researchers who enter into consulting agreements should familiarize themselves with Penn policies relevant to consulting activities. The researcher is expected to ensure that the terms of the consulting arrangement are consistent with Penn policies, including those related to intellectual property ownership, employment responsibilities and use of intellectual property. PCI is available (pciinfo@pci.upenn.edu) to provide informal advice on how your consulting agreement relates to your University of Pennsylvania intellectual property and your duties to Penn as your employer.

What is the faculty commitment to Penn?

Your primary commitment as a faculty member is to Penn. A consulting agreement with an outside party should never conflict with that obligation or other Penn policies or commitments.

For example, Penn faculty may not use more than an average of one in seven calendar days a week on outside consulting. Penn faculty should also inform their designated Technology Licensing Officer (TLO) of any proposed consulting arrangement so that the agreement can be reviewed for possible conflicts and can be directed to appropriate Penn personnel.

How is the Scope of Consulting determined?

The scope of consulting responsibilities should be very specific so that it does not grant the company inappropriate access to work done outside the consulting agreement, interfere with publications resulting from your academic work that overlap with your work responsibilities and obligations on University matters, or limit academic freedom.

What are considerations for a Consulting Contract?

The consulting agreement is a legal document drawn up by the company's lawyers. Faculty are strongly advised to have their own attorney review the document before signing, but may confer with Penn legal counsel as well solely to assess the proposed agreement's consistency with Penn policies. Faculty in the Perelman School of Medicine should disclose any proposed consulting arrangements to PSOM and faculty in other schools should bring their proposed consulting arrangements to the attention of the Legal Affairs Group at PCI (pciinfo@pci.upenn.edu).

HOW IS INTELLECTUAL PROPERTY HANDLED WHEN CONSULTING?

The Penn Patent Policy states that, in general, title to all inventions created in the course of employment at Penn, or from work directly related to professional or employment responsibilities at Penn, or from work carried out on Penn time, or at Penn expense, or with substantial use of Penn resources under grants or otherwise, are assigned to and owned by the University. Accordingly, a consulting agreement must not grant the company access to ideas, confidential information, or inventions that are already obligated to the University, such as inventions that arise outside of consulting activities or are related to University activities.

It is your responsibility to ensure that your consulting agreements do not impose obligations on you that are inconsistent with your obligations to Penn. Before entering a consulting agreement you may contact your technology licensing officer to review any terms that may be inconsistent with your obligations to Penn and modifications that may be necessary to resolve the inconsistency and ensure that the company is aware of and accepts your primary obligations to Penn.



*“To succeed, jump as quickly at opportunities
as you do at conclusions.”*
— Benjamin Franklin



STARTUPS

What is a startup company and why choose to create one?

A startup is a new business entity formed to commercialize inventions through the development and eventual sale of products or services. Forming a startup company is a type of commercialization strategy; other commercialization strategies include licensing intellectual property or creating a contractual relationship with an established business. A few key factors when considering whether to form and launch a startup company or develop a business relationship with an existing company are:

- the stage of the technology and the level of current product or service development risk;
- the amount it will cost to develop a product to market versus the potential investment return;
- the potential for multiple products or services from the same technology;
- whether or not there is a sufficiently large competitive advantage and target market;
- the amount of room for new entrants in the market;
- potential revenues or funding sources sufficient to sustain and grow a company; and
- alignment with potential collaborators and/or acquirers.

In partnership with Penn inventors and entrepreneurs, PCI can help to evaluate these and other factors.

Who decides whether to form a startup?

The choice to establish a new company for commercializing Penn-owned intellectual property is typically a mutual decision made by PCI and the inventors of the technology in question. PCI provides a variety of new venture products and services to faculty and staff through its PCI Ventures group. A faculty or staff member at Penn can establish a business without the assistance of Penn as long as the faculty member and the business otherwise are compliant with Penn’s policies. A business created in partnership with Penn, or through independent means, must still take a license to any Penn-owned IP it intends to use.

What role does a founder usually play in a company?

Faculty founders generally may not take on fiduciary roles for the companies that they help to create (e.g. board seats, officer positions, full-time employment arrangements, etc.), but faculty founders do typically serve as advisors or consultants for the company, often chairing or participating in the Scientific Advisory Board of the company, while also maintaining their position at Penn. In very rare instances, a faculty member may choose to leave Penn and join the startup in a full time capacity.

WHAT ASSISTANCE AND RESOURCES ARE AVAILABLE TO THE COMPANY FOUNDER?

When a business is created working with the PCI Ventures team, Penn enters (through PCI) into a company formation agreement with the founder(s) and may provide:

- *company formation services to establish a legal private entity;*
- *management team recruitment;*
- *template legal agreements;*
- *business development (e.g. market research, marketing, IP strategy);*
- *capital acquisition (including UPtheOdds, a full support grant submissions program);*
- *third party service providers on a deferred fee basis (payroll, bookkeeping, insurance, etc.);*
- *development of a funding strategy, making introductions to potential investors, and organizing investor showcases; and*
- *business operations services.*

In addition to the extensive resources made available through PCI Ventures, PCI administers the Penn I-Corps Site, an accelerator program funded by the National Science Foundation, where teams interested in starting a business can explore the feasibility of their idea before launching a company.

How much of my time and effort will it take?

Starting a company generally requires a considerable amount of time and effort. Until the startup team is identified and engaged, the faculty or staff member will need to be deeply involved in the company formation process. After the management team is in place, effort is reduced but still required during fundraising (e.g. grant writing, partner or investor pitches and discussions), in transferring technology from the University to the business, and in University processes such as conflict of interest disclosure and reviews.

Can Penn accept equity in the company?

Penn can accept equity for its efforts to help establish the company and/or as part of the financial terms of a license for any young business requiring a license from Penn to practice Penn-owned intellectual property rights. Equity may be substituted for other types of license consideration, such as up-front licensing payments, that are often difficult for startups to bear. It is also a way for Penn to share some of the risk, and hopefully the upside, associated with the startups. A decision to take equity must make sense for both Penn and the company. In businesses created with the help of PCI Ventures, the University owns founders’ equity in the entity.

Will Penn pay for incorporating a startup company?

Penn covers virtually all of the startup costs for entities created through the UPstart program managed by the PCI Ventures Group. The only direct financial cost to the founder is a \$100 reimbursable deposit into the business bank account Penn helps to open.

In many cases, the faculty advisory role is shaped with the startup investors and management team based on the founder’s expertise and interests. As the company matures, additional investment is required, and the founder’s role may change. It is important to recognize that a faculty member’s ownership interest in or other relationships with a startup may create a conflict of interest that may affect the faculty member’s participation in research and other activities at Penn.

Faculty involvement in a startup that constitutes a significant financial interest as defined in the University of Pennsylvania Policy on Conflicts of Interest Related to Research must be disclosed as specified in the policy. The University of Pennsylvania Conflict of Interest Standing Committee (CISC) reviews potential conflict of interest in any of the faculty member’s research that is related to the financial interest. Student founders and postdoctoral fellows may choose to join the startup upon graduation or departure from Penn, but often do not have the experience or business skills to serve as the company’s sole manager.

What legal assistance is needed in creating a startup?

Legal assistance may be needed to register the new business and to establish its operating papers, which define the ownership and governance of the business. Corporate counsel may also be needed to negotiate agreements such as employment contracts, license agreements, non-disclosure agreement, etc.

In addition to corporate counsel, the startup may have its own intellectual property counsel to assist with corporate patent strategy, especially if the company will be involved in an area of crowded IP. The startup's counsel must be separate from Penn counsel, though it is advisable and recommended that the corporate counsel and Penn patent counsel work together to coordinate their respective activities.

Companies formed through PCI Ventures have facilitated access to a variety of start-up service providers, including attorneys, who will often work on a deferred fee basis. In addition, the companies have full access to the legal document library that contains more than 40 documents available for use.

What are the Intellectual Property considerations?

In cases where intellectual property is owned by Penn, a small business must obtain a license from Penn in order to practice the intellectual property rights regardless of whether or not the business was created with the assistance of PCI or PCI Ventures. Utilizing Penn's help in launching a business does not constitute an automatic license to practice University-owned intellectual property.

How is my company related to Penn?

Companies are private entities independent of the University, even in cases when PCI Ventures is involved in launching the company. Penn may be a shareholder in the business but it does not solely control or own the business. Conversely, the small business does not have automatic access to the Penn research enterprise or administrative support simply because Penn is an equity holder in the business. All relationships, such as sponsored research, must be documented in a separately negotiated agreement.

How does PCI facilitate startup formation and acceleration?

The PCI Ventures team within the Penn Center for Innovation provides a variety of paths for faculty, staff, and students who have an interest in being entrepreneurial but do not have the time or resources to pursue that interest on their own. PCI Ventures has built numerous programs designed to meet the varying needs of different projects with different levels of service available from their team. PCIV's suite of services and hands-on support promote entrepreneurship activities and help to incubate early-stage technology-based businesses as they make their way towards commercial success.

See the PCI Ventures website for more details:
pci.upenn.edu/pciventures/

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