CENTRAL MICHIGAN UNIVERSITY INVENTOR'S GUIDE

The Inventor's Guide to Technology Transfer outlines the essential elements of technology transfer at Central Michigan University (CMU). This guide is based on that for the University of Michigan and is reproduced here with permission. However, CMU is responsible for the content.

This guide is organized to answer the most common questions we typically field from our research community, and provides a broad overview of the tech transfer process and services available for researchers at CMU.

For more information, visit the Technology Transfer and Commercialization page on the Office of Research and Graduate Studies (ORGS) web site or call ORGS at 989-774-6777. An abbreviated version of the CMU process may be found in the Quick Guides to Intellectual Property and Commercialization and Patenting and Commercialization, on the ORGS web site.

OVERVIEW

What is technology transfer?

Technology transfer is the transfer of knowledge and discoveries, either between and among entities or individuals or to the public. It can occur through publications, educated students entering the workforce, exchanges at conferences, and relationships with industry, among other things. For the purposes of this guide, technology transfer refers to the formal licensing, disclosure, or exchange of technology under the guidance of professionals employed by universities, research foundations, or businesses.

Who is responsible for Tech Transfer at CMU?

At CMU the Vice President for Research and Innovation (VPRI) in the ORGS is the University Official charged with managing and commercializing CMU intellectual property (IP) through technology transfer. The VPRI works in concert with the dean(s) of the academic colleges of the faculty inventor(s)¹ responsible for creating the IP, and with the CMU Research Corporation (CMURC), if appropriate. CMURC partners with CMU to conduct commercial assessments of University IP and to help identify commercial partners to license CMU technology. CMU also contracts with external patent attorneys to do patentability surveys and to file for patent protection.

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

The reasons are unique to each researcher and may include:

- making a positive impact on society
- feeling a sense of personal fulfillment
- achieving recognition and financial rewards

¹ Throughout this manual, unless specifically described otherwise, the term **inventor** includes individuals listed on a patent as well as contributors who have shared in creating the value of any other intellectual property that is not patented.

- generating additional lab/departmental funding
- meeting the obligations of a research contract
- attracting research sponsors
- creating educational opportunities for students
- linking students to future job opportunities

How is technology transferred?

Technology is typically transferred through a license agreement in which the University grants rights in the defined technology to a third party for a period of years, often limited to a particular field of use and/or region of the world. The licensee (the third party licensing the technology) may be an established company or a new business start-up. Licenses include terms that require the licensee to meet certain performance requirements and to make financial payments to the University. These payments are used to provide support for further research, education, and participation in the tech transfer process. The distribution of revenues from license payments is described in the <u>CMU Intellectual</u> <u>Property Rights Policy</u>.

What is the Bayh-Dole Act?

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

THE TECH TRANSFER PROCESS

How do I work with ORGS?

We encourage you to contact ORGS and your dean as soon as you believe a specific research project has commercial potential. ORGS and CMURC (as appropriate) will assist you with questions related to marketability, funding sources, commercial partners, patenting and other protection methods, new business start-up considerations, University policies and procedures, etc.

What are the typical steps in the process?

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

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

2 Pre-Disclosure: An early contact with ORGS personnel to discuss your invention or discovery and to provide guidance with respect to the disclosure, evaluation, and protection processes described below.

3 Invention Disclosure: The written notice of invention or discovery to ORGS that begins the formal technology transfer process. An <u>Invention disclosure</u> remains a confidential document and should fully document your invention so that the options for commercialization can be evaluated and pursued.

4 Assessment: The period in which you and your ORGS representative review the invention disclosure, conduct patent searches (if applicable), and analyze the market and competitive technologies to determine the invention's commercialization potential. This evaluation process, which may lead to a broadening or refinement of the invention, will guide our strategy on whether to focus on licensing to an existing company or creating a new business start-up.

5 Protection: Patent protection, a common legal protection method, begins with the filing of a patent application with the U.S. Patent Office. Once a patent application has been filed, it typically requires several years and tens of thousands of dollars to obtain issued U.S. patents. Because of cost, CMU generally will not pursue patent protection outside the U.S. Other protection methods include copyright, trademark, trade secrets, and contractual use restrictions (e.g., for databases and materials).

6 Marketing: With your active involvement, ORGS/CMURC staff will identify candidate companies that have the expertise, resources, and business networks to bring the technology to market. This may involve partnering with an existing company or forming a start-up. Your active involvement can dramatically shorten this process.

7a Form a Start-up: If creation of a new business start-up has been chosen as the optimal commercialization path, ORGS/CMURC staff will work as business formation consultants to assist in planning, forming, and funding the start-up. Please note that CMU is under no obligation to license IP to the inventor(s). This is a business decision that depends upon an assessment of the inventor's ability to commercialize the IP independently of CMU resources.

7b Existing Business: If an appropriate and interested existing company, or companies, are selected as a potential licensee, ORGS/CMURC staff will work with those potential licensees to develop the appropriate financial and diligence terms to fully commercialize the technology. In many cases this is the most likely route to commercialization.

8 Licensing: A license agreement is a contract between CMU and a third party through which CMU's rights to a technology are licensed, without relinquishing ownership, for financial and/or other benefits. A license agreement can be used with either a new start-up business or with an established company. An option agreement is sometimes used to enable a third party to evaluate the technology for a limited time prior to making a decision about licensing. Licensing agreements for start-up companies contain

performance milestones with the continuation of the license being contingent on demonstrated progress towards commercialization.

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

10 Revenue: Revenues received by the University from licenses are distributed to schools, colleges, departments, units, central administration, and inventors to fund additional research and education and to encourage further participation in the tech transfer process.

How long does the tech transfer process take?

The process of protecting the technology and finding the right licensing partner may take months—or even years—to complete. The amount of time will depend on the development stage of the technology, the market for the technology, competing technologies, the amount of work needed to bring a new concept to market-ready status, and the resources and willingness of the licensees and the inventors.

How can I help in this process?

- Call ORGS at 989-774-6777 when you believe you have created or discovered something unique with potential commercial or research value.
- Complete and submit the <u>Invention Disclosure</u> Form (before publicly disclosing your technology or submitting a manuscript for review and publication). Inventions must be patented within 12 months of public disclosure. CMU will not pursue patent protection if there is not adequate time for review.
- Remember that according to both patent law and the CMU IP policy, CMU owns your invention. It is important to avoid disclosing information to people outside CMU or trying to negotiate with outside entities yourself, because this may hinder or preclude our ability to protect or commercialize your work (this does not apply to collaborators at other institutions who participated in the invention or discovery). If you are contacted by outside entities, you should immediately talk to ORGS so they can develop a Non-Disclosure Agreement (NDA). An NDA protects the University's interests (and yours as the inventor) while allowing discussions with commercial entities.
- On the Disclosure Form, include companies and contacts you believe might be interested in your invention or discovery. Studies have shown that over 70% of all licenses are executed with commercial entities known to the inventor, so your contacts can be extremely useful.
- Respond to ORGS and outside patent counsel requests in a timely manner. While some aspects of the patent and licensing process may require significant participation on your part, we will strive to make efficient use of your valuable time.

• Keep ORGS informed of upcoming publications or interactions with companies related to your intellectual property.

RESEARCH CONSIDERATIONS

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

Yes, but since patent rights are affected by these activities, it is important to submit an Invention Disclosure (discussed in next section) before communicating or disclosing your invention to people outside the CMU community. Be sure to inform the ORGS of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/masters thesis, publication, or other public presentation including the invention.

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

Yes, but it is important to document carefully the date and conditions of use so that we can determine if this use would influence the ownership and license rights of your subsequent research results. If you wish to obtain materials from outside collaborators, an incoming Material Transfer Agreement (MTA) should be completed and signed by the VPRI (please contact ORGS).

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

Yes. However, it is important to document items that are to be shared with others and the conditions of use. If you wish to send materials to an outside collaborator, an outgoing Material Transfer Agreement (MTA) should be completed for this purpose. It also may be necessary to have a Confidentiality or Non-Disclosure Agreement completed to protect your research results or other intellectual property. Contact ORGS to assist you in completing outgoing MTAs or Confidentiality/Non-Disclosure Agreements.

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

Any Sponsored Research Agreement should specify the intellectual property (IP) rights of both the sponsor and CMU. CMU generally retains ownership of the patent rights and other intellectual property resulting from federally sponsored research projects, but commercial sponsors may make funding conditional upon their retention of IP rights, or on having the rights to obtain a license to the defined and expected outcomes of the research within a specified period of time. Even so, the sponsor generally will not have contractual rights to discoveries that are clearly outside of the scope of the research. Therefore, it is important to define the scope of work within a research agreement.

What About Consulting?

Under the Collective Bargaining Agreement between CMU and the Faculty Association, regular faculty members are allowed to engage in outside consulting provided this does

not require CMU resources or involve a conflict of commitment or interest. Because consulting agreements are outside of the scope of employment, they are not negotiated by CMU nor formally reviewed by ORGS. However, researchers are strongly encouraged to contact their dean or ORGS prior to entering into consulting agreements that are related to their research expertise. This will help ensure the consulting arrangement is consistent with CMU policies, including those related to IP ownership, employment responsibilities, and use of Intellectual Property.

INVENTION DISCLOSURES

What is an Invention Disclosure?

An Invention Disclosure (ID) is a written description of your invention or development that is provided to your college and ORGS. The ID should list all collaborating sources of support and include all of the information necessary to begin pursuing protection, marketing, and commercialization activities.

This document will be treated as confidential. Based on the Invention Disclosure, ORGS/CMURC may generate a non-confidential description of your invention in order to assist in marketing the technology. Once potential partners have been identified, and confidentiality agreements have been signed, more detailed exchanges of information can be made.

Why should I submit an Invention Disclosure?

When you disclose your invention to ORGS, it starts a process that could lead to the commercialization of your technology. This may involve beginning the legal protection process and working to identify outside development partners. If government funds were used for your research, you are required to file a prompt disclosure, which will be reported to the sponsoring agency. Similar requirements may exist for other sponsored projects.

How do I know if I should submit an Invention Disclosure?

You are encouraged to submit an Invention Disclosure for all inventions and developments that you feel may solve a significant problem and/or have significant value. If you are in doubt, contact ORGS to discuss the invention and strategies for commercialization.

When should I complete an Invention Disclosure?

You should complete an Invention Disclosure whenever you feel you have discovered or created something unique with possible commercial value. This should be done well before presenting the discovery or invention through publications, poster sessions, conferences, press releases, or other communications. Once publicly disclosed (i.e., published or presented in some form), an invention or discovery may have restricted or minimal potential for patent protection outside of the United States. Differences exist between the U.S. and other countries on the impact of early publication on a potential patent. Be sure to inform ORGS of any imminent or prior presentation, lecture, poster,

abstract, website description, research proposal, dissertation/masters thesis, publication, or other public presentation that contains reference to or a description or disclosure of the invention or discovery.

Should I disclose research tools?

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

How do I submit an Invention Disclosure?

Complete the <u>Invention Disclosure</u> form and send it to the VPRI in ORGS. If you have any questions, call ORGS at 989-774-6777.

OWNERSHIP OF INTELLECTUAL PROPERTY

What is "intellectual property"?

Intellectual property includes, but is not limited to, inventions, discoveries, and/or material that may be protected under the patent, trademark and/or copyright laws, and sometimes by contract.

Who owns what I create?

Ownership depends upon the employment status of the creators of the invention and their use of CMU facilities or resources. Considerations include what:

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

As a general rule, CMU owns inventions made by its employees while acting within the scope of their employment or using University resources. Details can be found in the the <u>CMU Intellectual Property Rights Policy</u>. In some cases, the terms of a Sponsored Research Agreement or Materials Transfer Agreement may affect ownership. When in doubt, it is best to call ORGS for advice.

Who owns rights to inventions or discoveries made while I am consulting?

The ownership of inventions made while consulting for an outside company depends on the terms of your consulting contract. It is important to clearly define the scope of work within consulting contracts to minimize any issues with ownership of inventions created from CMU research.

Who owns rights to inventions or discoveries made while on sabbatical?

Generally, if you are on a sabbatical paid by CMU, CMU retains rights to any discoveries or inventions connected to your scope of employment. Contact ORGS before your sabbatical to ensure that ownership considerations are documented.

Should I list visiting scientists or scientists at other institutions on my Invention Disclosure?

All contributors to the ideas leading to an invention or discovery should be mentioned in your disclosure, even if they are not CMU employees. ORGS, along with legal counsel, will determine the rights of such persons and institutions. It is prudent to discuss with ORGS all working relationships (preferably before they begin) to understand the implications for any subsequent inventions.

Can a student contribute to an invention or discovery?

Yes, many students work on inventions or make discoveries at CMU under a wide variety of circumstances. Typically, a student will own his or her rights to an invention unless the invention was created by a student in a capacity as an employee, the student used more than incidental CMU resources, or the student signed an IP agreement prior to working on the project.

Assessment of an invention disclosure

How does CMU assess Invention Disclosures?

Staff at ORGS (and CMURC, as appropriate) examine each invention disclosure to review the novelty of the invention or discovery, protectability and marketability of potential products or services, relationship to existing intellectual property, size and growth potential of the relevant market, amount of time and money required for further development, pre-existing rights associated with the intellectual property (IP), and potential competition from other products/technologies.

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

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

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

Generally, ORGS supports CMU software developers who choose to essentially give their programs away through open source mechanisms, provided that CMU retains the right to distribute the program freely, that open sourcing is consistent with obligations to sponsors, and that each developer's unit supports the decision. Developers should seek authorization from their dean.

Is an invention or discovery ever assigned to an Inventor?

If CMU decides not to pursue patent protection and/or chooses not to actively market the invention, CMU may transfer ownership to the inventor(s). Reassignment of inventions funded from U.S. government sources requires the government's prior approval. It is important to understand that if you are assigned your invention you can not use CMU resources including space to continue research, build prototypes, etc. The transfer of an invention is contingent on the inventor(s) developing an acceptable plan indicating how future development will be done independently of their CMU responsibilities and CMU resources, recognizing that in many cases it may not be feasible to separate an invention from one's ongoing CMU research.

PATENTS AND OTHER LEGAL PROTECTION

What is a patent?

In the U.S., a patent gives the holder the right to exclude others from making, using, selling, offering to sell, and importing the patented invention or discovery. A patent does not necessarily provide the holder any affirmative right to practice a technology since it may fall under a broader patent owned by others. Instead, it provides the right to exclude others from practicing the invention or discovery. Patent claims are the legal definition of an inventor's protectable invention or discovery.

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, articles, and even performing business.

Can someone patent a naturally occurring substance?

Generally, no. A natural substance that has never before been isolated or known may be patentable in some instances, but only in its isolated form (since the isolated form had never been known before). A variation of a naturally occurring substance may be patentable if an inventor is able to demonstrate substantial non-obvious modifications that offer advantages of using the variant.

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

The PTO is the federal agency, organized under the Department of Commerce, that administers patents on behalf of the government. The PTO employs patent examiners skilled in all technical fields in order to appraise patent applications. The PTO 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 ideas in the patent claims of a patent application. Thus, inventorship of a patent application may change as the patent claims are changed during prosecution of the application. An employer or person who furnishes money to build or practice an invention is not an inventor. Inventorship is a legal issue and may require an intricate legal determination by the patent attorney prosecuting the application. It is important to understand that as a CMU employee you may be an inventor, but this is separate from ownership of the invention, which resides with CMU.

Who is responsible for patenting?

ORGS contracts with outside patent counsel for patent protection, thus assuring access to patent specialists in diverse technology areas. Inventors work with ORGS and patent counsel in drafting the patent applications and responses to worldwide patent offices.

What is the patenting process?

Patent applications are generally drafted by a patent attorney or a patent agent (a nonattorney with a science education licensed to practice by the PTO). The patent attorney generally will ask you to review an application before it is filed and will also ask you questions about inventorship of the application claims. In about one year or longer, depending on the technology, the patent attorney will receive written notice from the PTO as to whether the application and its claims have been accepted in the form as filed. More often than not, the PTO rejects the application because either certain formalities need to be cleared up, or the claims are not patentable over the "*prior art*" (anything that workers in the field have made or publicly disclosed in the past). The letter sent by the PTO is referred to as an Office Action or Official Action.

If the application is rejected, the patent attorney must file a written response, usually within three to six months. Generally, the attorney may amend the claims and/or point out why the PTO's position is incorrect. This procedure is referred to as patent prosecution. Often it will take multiple PTO Official Actions and responses by the patent attorney before the application is resolved. The resolution can take the form of a PTO notice that the application is allowable; in other words, the PTO 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. The PTO holds patent applications confidential until published by the PTO, 18 months after initial filing.

Is there such a thing as a provisional patent?

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

What is the difference between a provisional patent application and a regular (or "utility") patent application?

In certain circumstances, U.S. provisional patent applications can provide a tool for preserving patent rights while temporarily reducing costs. This occurs because the application is not examined during the year in which it is pending and claims are not required. A regular U.S. application and related foreign applications must be filed within one year of the provisional form in order to receive its early filing date. However, an applicant only receives the benefit of the earlier filing date for material that is adequately

described and enabled in the provisional application. As a result, the patent attorney may need your assistance when an application is filed as a provisional.

What's different about foreign patent protection?

Foreign patent protection is subject to the laws of each individual country, although in a general sense the process works much the same as it does in the United States. In foreign countries, however, an inventor will lose any patent rights if he or she publicly discloses the invention prior to filing the patent application. In contrast, the United States has a one-year grace period.

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. 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. The PCT application must later be filed in the national patent office of any country in which the applicant wishes to seek patent protection, generally within 30 months of the earliest claimed filing date.

Does CMU patent inventions overseas?

Generally, CMU only patents inventions in the US, which provides protection within the US, including prohibiting import of the patented invention made overseas. This strategy is based on the high cost of obtaining patent protection in multiple countries.

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

Currently, the average U.S. utility patent application is pending for about two years, though inventors in the biotech and computer fields should plan on a longer waiting period. Once a patent is issued, it is enforceable for 20 years from the initial filing of the application that resulted in the patent, assuming that PTO-mandated maintenance fees are paid.

Why does CMU protect some intellectual property through patenting?

Patent protection is often a requirement of a potential commercialization partner (licensee) because it can protect the commercial partner's often sizable investment required to bring the technology to market. Due to their expense and the length of time required to obtain a patent, patent applications are not possible for all CMU intellectual property. We carefully review the commercial potential for an invention before investing in the patent process.

Who decides what gets protected?

ORGS and the inventor(s) consider relevant factors in making recommendations about filing patent applications. The VPRI ultimately makes the final decision as to whether to file a patent application in consultation with the inventor(s), dean(s) and CMURC.

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

Filing a regular U.S. patent application may cost between \$10,000 and \$20,000. To obtain an issued patent may require an additional \$10,000 to \$15,000 for patent prosecution. Filing and obtaining issued patents in other countries may cost \$20,000 or more per country. Also, once a patent is issued in the U.S or in foreign countries, certain maintenance fees are required to keep the patent alive.

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 ORGS 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, ORGS will usually enter into an "inter-institutional" agreement that provides for one of the institutions to take the lead in protecting and licensing the invention, sharing of expenses associated with the patenting process and allocating any licensing revenues. If the technology is jointly owned with another company, ORGS will work with the company to determine the appropriate patenting and licensing strategy.

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

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

What is a copyright and how is it useful?

Copyright is a form of protection provided by the laws of the United States to the authors of "original works of authorship." This includes literary, dramatic, musical, artistic, and certain other intellectual works as well as computer software. This protection is available to both published and unpublished works. Generally, both by operation of law and according to CMU's Intellectual Property Policy, CMU is the copyright owner for any works created by a CMU employee within the scope of their employment. There are some cases where CMU will not assert copyright ownership; those can be found in the Policy. The Copyright Act generally gives the owner of copyright the exclusive right to conduct and authorize various acts, including reproduction, distribution, public performance, public display, and making derivative works. Copyright protection is automatically secured when a work is fixed into a tangible medium of expression such as a book, software code, video, etc. In some instances, CMU registers copyrights, but generally not until a commercial product is ready for manufacture.

What is a derivative work?

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

work of authorship, is a "derivative work." The owner of a copyright generally has the exclusive right to create derivative works.

How do I obtain a copyright?

CMU will determine, in consultation with the creator, whether to file an application with the U.S. Copyright Office. If a copyright is pursued, the author is expected to cooperate in filing the necessary paperwork, which will be provided by ORGS. All costs will be paid by CMU. If the work was created within the scope of employment and is not subject to an exemption in CMU's Intellectual Property Policy, CMU will be the owner of the copyright, though the author or creator will be given appropriate credit.

CONSIDERATIONS FOR A START – UP COMPANY

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

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

- Development risk (often companies in established industries are unwilling to take the risk);
- Development costs versus investment return (can the investors obtain their needed rates of return);
- Potential for multiple products or services from the same technology (few companies survive on one product alone);
- Sufficiently large competitive advantage and target market;
- Potential revenues sufficient to sustain and grow a company

ORGS and CMURC will work with faculty inventor(s) and dean(s) can help evaluate these and other factors.

Who decides whether to form a start-up?

The choice to establish a new company for commercializing IP is a joint decision made by ORGS and dean(s) of college(s) involved with input from CMURC and the inventor(s). If a new business start-up is chosen as the preferred commercialization path, CMURC new business development specialists will assist you in planning and executing the process. These staff members act as business formation consultants, providing handson assistance and access to outside resources.

How does forming a start-up affect my position at CMU?

Participation in a start-up company based on technology you invented and licensed from CMU does not necessarily affect your role at the University. As part of the licensing agreement CMU will specify terms and conditions that will include: waiving your rights to royalty revenues that accrue to CMU; defining boundaries between involvement with the company and your other research obligations to CMU; identifying and remedying issues related to conflict of interest and commitment.

What assistance and resources are available to the inventor?

The CMURC new business development specialists and consultants serve as coaches, advisors, resource locators and project planners to help fill the gap between the technology and the formation of a start-up. Their activities may include locating progressive management talent, developing a funding strategy, making introductions to probable investors, reviewing business plans, and engaging experts to work on key gating issues. New business development professionals can also draw upon an extensive network of resources and experience to assist you.

What role does an inventor usually play in a company?

CMU faculty typically serve as technology consultants, advisors or in some other technical developmental capacity. Rarely do faculty choose to leave the University and join the start-up. In many cases, the faculty role is suggested by the start-up investors and management team who identify the best role based on the inventor's expertise and interests. As the company matures, and additional investment is required, the inventor's role may change. Faculty involvement of any kind in a start-up is also reviewed by the CMU Conflict of Interest Committee. Student inventors and post-docs may choose to join the start-up upon graduation but rarely have the experience or business skills to serve as the company's sole management.

How much of my time and effort will it take?

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

Can CMU accept equity in the company?

The University can accept equity as part of the financial terms of the license. Equity may be substituted for other cash considerations that are often difficult for start-ups. It is also a way for the University to share some of the risk associated with the start-ups. A decision to take equity must make sense for both the University and the company.

Will CMU pay for incorporating a start-up company?

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

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

In addition to corporate counsel, the start-up may have its own intellectual property counsel to assist with corporate patent strategy, especially if the company will be involved in a patent-rich area. The start-up's counsel must be separate from CMU counsel, though it is advisable and recommended that the corporate IP Counsel and the CMU Patent Counsel coordinate activities. Also, it is wise for inventors to have agreements regarding their roles with the start-up reviewed by their own counsel to

ensure that all personal ramifications—including taxation and liabilities—are clearly understood.

MARKETING TO FIND A LICENSEE

How does ORGS market my inventions?

CMURC staff use many sources and strategies to identify potential licensees and market inventions. Sometimes existing relationships of the inventors, ORGS and CMURC staff, and other researchers are useful in marketing an invention. Market research can assist in identifying potential licensees. We also examine other complementary technologies and agreements to assist our efforts. CMURC may also use their website to post inventions, leverage conferences and industry events, and make direct contacts. Faculty publications and presentations are often excellent marketing tools as well.

How are most licensees found?

Studies have shown that 70% of licensees were already known to the inventors. Thus research and consulting relationships are often a valuable source for licensees. Licensees are also identified through existing relationships of the CMURC staff. We attempt to broaden these relationships through contacts obtained from website posting inquiries, market research, industry events and the cultivation of existing licensing relationships.

How long does it take to find a potential licensee?

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

How can I assist in marketing my invention?

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

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.

LICENSES AND OTHER AGREEMENTS

What is a license?

A license is a permission that the owner or controller of intellectual property grants to another party, usually under a license agreement.

What is a license agreement?

License agreements describe the rights and responsibilities related to the use and exploitation of intellectual property developed at CMU. CMU license agreements usually stipulate that the licensee should diligently seek to bring the intellectual property into commercial use for the public good and provide a reasonable return to CMU. In many cases the agreement will have explicit milestones that the licensee must meet to retain the license.

How is a company chosen to be a licensee?

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

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

Per CMU policy, a share of any financial return from a license is provided to the inventor(s). This is described in the <u>CMU Intellectual Property Policy</u>. Most inventors enjoy the satisfaction of knowing their inventions are being deployed 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. In some cases, additional sponsored research may result from the licensee.

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

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

What other types of agreements and considerations apply to tech transfer?

• Non-Disclosure Agreements (NDAs) are often used to protect the confidentiality of an invention during evaluation by potential licensees. NDAs also protect proprietary information of third parties that CMU researchers need to review in order to conduct

research or evaluate research opportunities. ORGS enters into NDAs for CMU proprietary information shared with someone outside of CMU.

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

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

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

• Research Agreements describe the terms under which sponsors provide research support to the University.

COMMERCIALIZATION

What activities occur during commercialization?

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

What is my role during commercialization?

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

What revenues are generated for CMU if commercialization is successful? If unsuccessful?

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

offering or a sale of the company) occurs. Most licenses do not yield substantial revenues. A recent study of licenses at U.S. universities demonstrated that only 1% of all licenses yield over \$1 million so don't but that retirement home in Maui just yet. However, the rewards of an invention reaching the market are often more significant than the financial considerations alone.

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

Licenses typically include performance milestones that, if unmet, can result in termination of the license. This termination allows for subsequent licensing to another business.

NAVIGATING CONFLICT OF INTEREST

How does CMU define a conflict of interest?

A conflict of interest can occur when a CMU employee, through a relationship with an outside organization, is in a position to:

- 1) Influence CMU's business, research or other areas that may lead to direct or indirect financial gain to the employee;
- 2) Adversely impact or influence one's research or teaching responsibilities;
- 3) Provide improper advantage to others, to the disadvantage of CMU.

When should I seek guidance on conflict of interest?

Whenever a question or uncertainty arises, you should seek guidance from your Dean or ORGS. There are two times in particular when guidance is required: when research proposals are submitted to external agency; and when a license, option, or MTA is being considered with a company in which the faculty member, or any university employee, has an equity or management interest.

What kinds of issues concern conflict of interest reviewers?

Examples include the appropriate and objective use of CMU research or resources for personal gain, the treatment and roles of students, supervision of individuals working at both CMU and a licensee company, and conflict of commitment (i.e., your ability to meet your CMU obligations).

What are examples of a conflict of commitment?

A conflict of commitment may exist if duties, assignments or responsibilities associated with a technology license or outside business arrangement have a negative impact on your ability to meet commitments associated with your CMU employment or exceed the amount of time available to you for these activities. The best approach is to fully disclose your situation to your supervisor and discuss the implications for your job responsibilities.

How does CMU manage conflict associated with research and tech transfer transactions?

ORGS representatives can advise you on conflict of interest issues or refer your case to the Conflict of Interest (COI) Committee. It is the responsibility of the researcher or faculty member to disclose and document any outside arrangements that constitute situations or interests as described in CMU's conflict of interest policies. A conflict of interest disclosure can be made to the COI that will review the situation and develop a conflict management plan. COI approval is required before any associated agreements can be approved.

REVENUE DISTRIBUTIONS

How are license revenues distributed?

ORGS is responsible for managing the expenses and revenues associated with technology agreements. Per the <u>CMU Intellectual Property Policy</u>, revenues from license fees, royalties and equity—minus any unreimbursed patenting and file expenses—are shared with inventors.

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

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

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

Revenues waived by inventors are distributed to the associated school/college and department/unit. To avoid potential tax liability, revenues waived by you to your department/unit must not be under your control. See ORGS for additional information.

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

While there may be some variation in the procedure, typically when a license agreement is developed, a Revenue Distribution Plan (RDP) is created to document the formula used to distribute any subsequent revenues. The initial RDP includes a draft formula based on the contributions listed in the Invention Disclosure(s) relating to the license. ORGS asks one inventor within the group to serve as coordinator and to report the percentages determined by the inventors collectively. All inventors must sign the RDP, signifying their approval. Should the inventors be unable to agree on a revenue distribution plan, ORGS will make the final revenue allocation decision.

How is equity from a license distributed?

When University equity is liquidated by the University Treasurer's office, the resulting funds are distributed in accordance with the RDP and University Policy. Shares of publicly traded businesses may be distributed to inventors before liquidation.