



**Mount
Sinai**

INNOVATION PARTNERS

OCTOBER 2015



THE INVENTORS GUIDE

A Handbook for Faculty, Staff
and Trainees of the Mount Sinai
Health System in New York City

INNOVATION PARTNERS 2014 METRICS

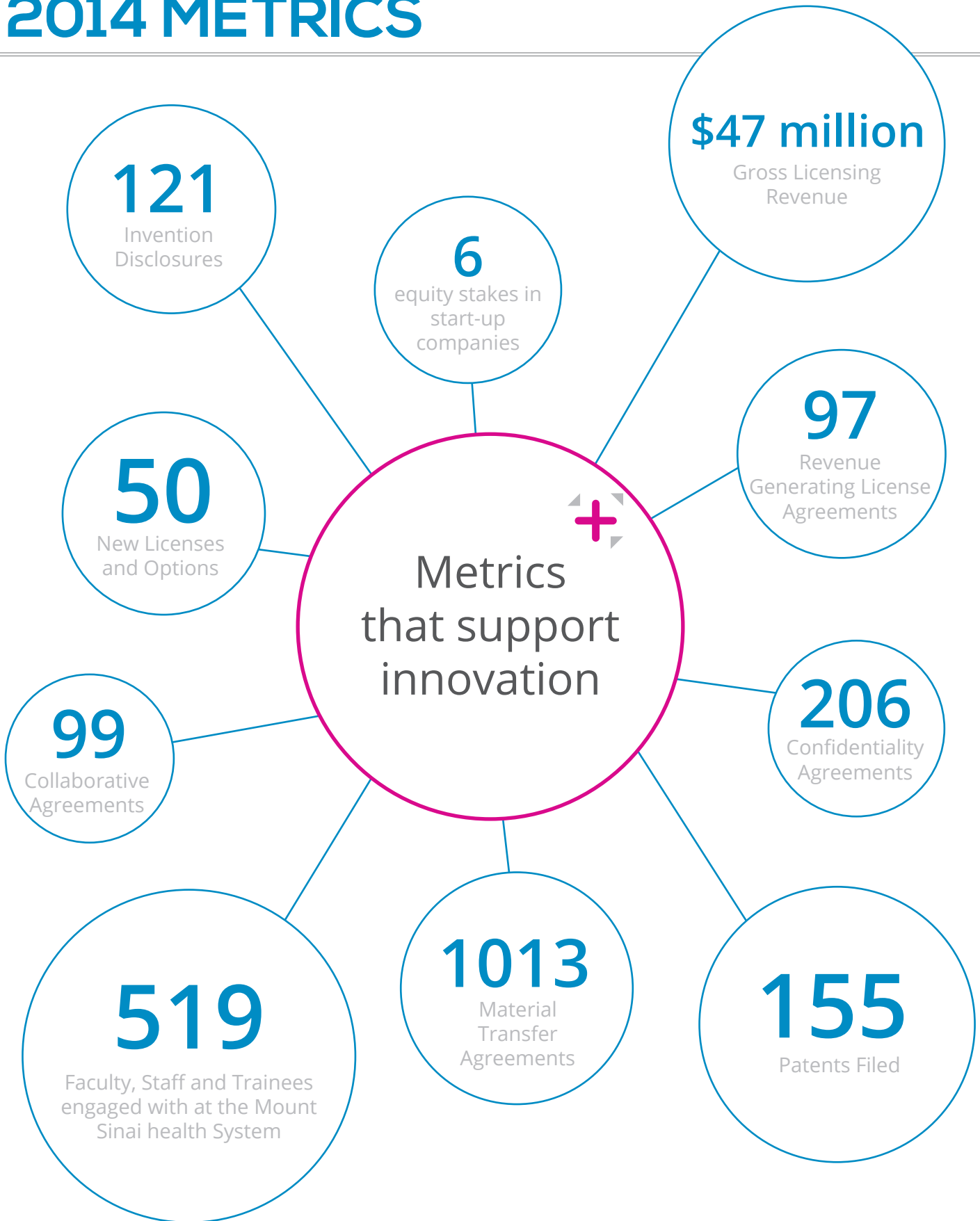


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This guide was drafted by Mount Sinai Innovation Partners (MSIP) in collaboration with Dr. Scott Friedman, Dean for Therapeutic Discovery, and is based upon the University of Michigan Office of Technology Commercialization's "Inventor's Guide to Technology Commercialization". Dr. Friedman, Mount Sinai and MSIP thank the University of Michigan for permission to use its copyright.

TECHNOLOGY DEVELOPMENT AND COMMERCIALIZATION

The Inventors Guide outlines the essential elements of technology development and commercialization at the Mount Sinai Health System.

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

What is innovation? What constitutes innovative technology?

Innovation is the creation of better products, processes, or approaches for an identified job or function. Innovative technologies can be more effective, safer, and/or cheaper than pre-existing technologies. Innovative technologies can also create new markets and/or demand.

What is a 'disruptive' technology?

A disruptive technology, a term originally coined by Harvard Business School Professor Clayton Christensen, represents an innovation that upends a market and displaces current technologies to the point they become almost obsolete. Disruptive technologies are highly attractive to investors because of their ability to create high value and to expand markets. An example of a 'disruptive' technology in the healthcare industry includes the advent of monoclonal antibodies as therapeutics.

How does Mount Sinai support innovative activities?

Mount Sinai is very supportive of creativity and innovation as a means to bring about new medicines and effective clinical approaches for the public good. Mount Sinai Innovation Partners (MSIP) support Mount Sinai faculty, staff and trainees in technology development and commercialization. In addition, events will be planned throughout the year to provide additional education and support for the faculty and trainees in their technology development efforts.

What is technology transfer?

Technology transfer is the transfer of knowledge and discoveries to the public. It can occur through publications, educational seminars, exchanges at conferences, and relationships with industry, among other things. For the purposes of this guide, technology transfer refers to the formal licensing of technology to third parties under the guidance of professionals employed by universities, research foundations, and businesses.

Who is Mount Sinai Innovation Partners?

Mount Sinai Innovation Partners (MSIP) is a service unit of the the Mount Sinai Health System composed of specialists in

licensing, business development, marketing, financial and legal matters whom are experienced in transferring technologies from the health and life sciences. MSIP is responsible for managing technology disclosures from faculty and staff of Mount Sinai. In addition, MSIP seeks to foster productive relationships with industry and life science investors to bring complementary skills and resources to Mount Sinai to accelerate innovation. Some of the tasks of the office include intellectual property assessments, commercial market analysis, patent preparation and prosecution, contract negotiations, alliance management and post deal finance and contract management.

How does MSIP foster relationships with industrial partners?

MSIP seeks to increase industrial relationships by four broad categories of activity:

- Raising the awareness of the faculty to the opportunities for and the mechanism of obtaining industrial support;
- Increasing the awareness of industry to Mount Sinai's intellectual property, faculty and organization assets;
- Proactively seeking and effectively negotiating agreements with industry; and
- Contributing to the Schools' strategic development in technology commercialization and industrial collaboration.

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

The reasons are unique to each researcher and may include:

- Introducing new ideas and products that enhance science and medicine;
- Making a positive impact on society;
- Feeling a sense of personal fulfillment;
- Generating additional lab/departmental funding;

- Meeting the obligations of a research contract;
- Attracting research sponsors;
- Creating educational and job opportunities for students and post-docs; and
- Achieving recognition and financial rewards.

How is technology transferred?

Technology is typically transferred through a license agreement in which Mount Sinai grants its rights in the defined technology to a third party for a period of years, often limited to a particular field of use and/or region of the world. The licensee (the third party licensing the technology) may be an established company or a new business start-up. Licenses include terms that require the licensee to meet certain performance requirements and to make financial payments to Mount Sinai. These payments are shared with the inventors and are also distributed to Mount Sinai and its departments/institutes to provide support for further research, education, and participation in the tech transfer process. The percent distributed to the various entities can be found in the faculty handbook. (See Section 4.19. Royalty Distribution – General under the [Policies on Intellectual Property](#): Ownership and Commercial Development)

What is the Bayh-Dole Act?

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

**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 intellectual property that is not patented.

WHY INVENT?

INVENTIONS TRANSLATE DISCOVERIES INTO SOLUTIONS, WHICH:



OWNERSHIP OF INTELLECTUAL PROPERTY

What is “intellectual property”?

Intellectual property is inventions and/or material that may be protected under the patent, trademark and/or copyright laws, and sometimes by contract.

Who owns what I create?

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

According to the Faculty Handbook (See Section 2.1. Technology Ownership Policy Statement under the [Policies on Intellectual Property: Ownership and Commercial Development](#)) Mount Sinai will own Technology made or created by Mount Sinai faculty, students, staff, visitors, employees, volunteers and others participating in Mount Sinai programs except for Technology that is owned by the Inventors/Authors. Inventors/Authors will own Technology that is:

1. Developed outside the area of research of the Inventor/Author conducted under a sponsored Research Project
2. Not created as a “work-for-hire” by operation of copyright law or not created pursuant to a written agreement between the Author/Inventor and Mount Sinai providing for a transfer of copyright, patent or other intellectual property right ownership to Mount Sinai or a third party; and
3. Not developed with the use of funds or facilities administered by Mount Sinai.

Mount Sinai’s copyright policy describes the applicable rules for copyrightable works (see section 2.1. Technology Ownership under the [Policies on Intellectual Property: Ownership and Commercial Development](#)). In some cases, the terms of a Sponsored Research Agreement or Materials Transfer Agreement may impact ownership. When in doubt, it is best to contact your MSIP representative for advice. If you do not have an assigned MSIP representative, call MSIP at 646-604-7301 or visit www.ip.mountsinai.org.

Who owns rights to 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 Mount Sinai research. If you have questions, please contact Kenneth Brower, Director Conflicts

of Interest Office, at 212-241-0845 or kenneth.brower@mssm.edu.

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

All contributors to the ideas leading to a discovery should be mentioned in your disclosure, even if they are not Mount Sinai employees. MSIP, along with patent counsel, will determine the rights of such persons and institutions and work out the necessary arrangements with appropriate third party institutions. It is prudent to discuss with MSIP all working relationships (preferably before they begin) to understand the implications for any subsequent inventions.

Can a student contribute to an invention?

Yes, many students work on inventions at Mount Sinai under a wide variety of circumstances. Mount Sinai promotes student entrepreneurship, and students can be named as Inventors under Mount Sinai Policy. Mount Sinai (see section 2.1. Technology Ownership under the [Policies on Intellectual Property: Ownership and Commercial Development](#)). As stated previously, Mount Sinai owns inventions made or created by the faculty, students, staff, visitors, employees, volunteers and others participating in Mount Sinai programs while acting within the scope of their employment or using Mount Sinai funds or facilities.



PATENTS AND 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. 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. Patent claims are the legal definition of an inventor'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 making articles, and even methods of 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 (USPTO)?

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

Who is an inventor?

An inventor is one who contributes to the conception of an invention. The patent law of the United States of America requires that the applicant in a patent application must be the inventor. If you have directly contributed to the development of a potentially patentable discovery you are an inventor. In order to complete a patent application an inventor(s) must sign an Oath of Declaration. The Oath of Declaration provides evidence to the USPTO that you are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought. Failure to execute an Oath of Declaration will deem the application abandoned.

Who will guide me through the patenting process?

You will be assigned a manager who along with the Patent

Group of MSIP will help guide and assist you through the patenting process. The members of the Patent Group are specialists in the patenting process and in collaboration with our patent attorneys can answer any questions you may have to make certain your application moves through the USPTO with ease.

What is the patenting process?

A patent application must be presented to the USPTO in a standardized format. We partner with patent attorneys who specialize in patent prosecution and who have advanced scientific backgrounds. During the drafting of a patent application our attorneys will collaborate with you to draft and finalize a description of your discovery, claims and drawings. When the application is final and ready for filing you will be asked to execute formal documents such as an Oath of Declaration. The Oath of Declaration provides evidence to the USPTO that you are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought. You will also be asked to disclose your awareness of any patent applications or non-patent literature or "prior art" that are similar to your subject matter. You will have a continuing duty to disclose to the patent office any prior art you become aware of.

In about one year a USPTO patent examiner will examine your application and raise certain issues about your application in the form of an Office Action. An issued Office Action sets a 3-month deadline whereby we must respond to the examiners objections. We may extend the time for a response by payment of fees. A response to an Office Action may include an amendment to the specification and/or claims and must distinguish your application from any prior art or raised issues by the examiner. Our attorneys will again collaborate with you to provide evidence and support for a response to an issued Office Action.

What is a US Provisional Patent Application?

A US Provisional Patent Application provides a means to establish an early effective filing date. A provisional patent application does not get examined, will not publish and will not progress to an issued patent application. A provisional application will expire 12-months from the filed date. Prior to expiration of a provisional application you will be contacted by the OTBD to advise on any updates to your discovery, whether a viable commercial partner has been identified and if further financial investment is warranted.

MSIP takes advantage of provisional applications as a cost delay strategy to provide time for identifying and negotiating with commercial entities.

What is a PCT Application?

A PCT (Patent Cooperation Treaty) application is an international application that provides a mechanism by which an applicant can file a single patent application that is equivalent to filing a patent application in each of the contracted states of the PCT including the United States. There are currently 146 member countries contracted with the PCT. A PCT application will not progress as an issued international application. A PCT application delays the time to continue and file the application in foreign countries and allows for the opportunity to develop and to evaluate time and/or market the invention for licensing. A PCT application will expire 18-months from the international file date.

Soon after publication of the international application the International Searching Authority (ISA) will examine the application and offer an International Search Report and Written Opinion. The Written Opinion will provide us clues as to the novelty, inventive step and industrial applicability of the application. It will also provide us guidance of any similar patents and/or non-patent literature ("Prior Art") that should we decide to continue we would have to distinguish ourselves against.

MSIP takes advantage of the PCT filing process as a cost effective filing strategy to provide time for identifying and negotiating with commercial entities. During the next year and a half MSIP will work with you to market and commercialize the application. Together we will work on the identification of a commercialization partner.

What is a National Phase Entry?

Entry into the National Phase of the patenting process represents a significant financial investment in a patent application. It is at this stage when we must make a decision to enter the application into foreign countries including the United States. We ideally would have found a commercial partner at this stage and they will guide us as to which countries they are interested in extending international patent protection.

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 USPTO-mandated maintenance fees are paid.

Why does Mount Sinai 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 Mount Sinai intellectual property. We carefully review the commercial potential for an invention before investing in the patent process. However, because the need for commencing a patent filing usually precedes finding a licensee, we look for creative and cost-effective ways to seek early protections for as many promising inventions as possible recognizing that many of these may need to be abandoned once commercial viability is more apparent.

Who decides what gets protected?

The decision to file a patent application is based on the commercial potential of the idea being considered for patenting and the potential for positive patient and societal impact, as well as financial impact for Mount Sinai. The final decision to pursue patent or other intellectual property protection is made by MSIP in consultation with internal and external experts and in cooperation with the inventor(s).

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.

US/PCT PATENT PROCESS

The flow chart below represents Mount Sinai's patent filing strategy which opens collaboration entry points for commercialization. Significant deadlines are highlighted at the 12-month and 30-month conversion points where Mount Sinai will make important financial decisions on whether the application will move along the process.



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

Will Mount Sinai initiate or continue patenting activity without an identified licensee?

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

What is a copyright and how is it useful?

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

What is a derivative work?

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

How do I represent a proper Mount Sinai copyright notice?

Although copyrightable works do not require a copyright

notice, we recommend that you use one. The following notice is to be applied on Mount Sinai owned works to protect the copyright:

“Copyright © 20XX ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI. All rights reserved.”

The date in the notice should be the year in which the work is first published. No notice other than the foregoing is to be used for Mount Sinai owned works. Further, for added copyright protection, certain works may be registered with the United States Copyright Office using its official forms.

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

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

A trade or service mark may be used to protect those names and symbols associated with certain Mount Sinai activities and events and with certain technology developments such as computer programs. Prior to registration for trademark protection, the designation “TM” after a trademark or “SM” after a service mark will give adequate notice of a claim of ownership. The designation “®” for a trademark may only be used after federal registration.

Request for use and registration of trade and service marks to protect Mount Sinai owned technology or to designate Mount Sinai as the origin of a product or service may be initiated through MSIP, and may require coordination with other Mount Sinai units. Trademark protection carries with it certain obligations on the part of the holder of the mark and these obligations may need to be reflected in any agreements and use of the mark.

What is trademark registration?

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

COMMERCIALIZATION PROCESS AT MOUNT SINAI

How do I work with Mount Sinai Innovation Partners?

We encourage you to contact MSIP during your early research activities to be aware of the options that will best leverage the commercial potential of your research. MSIP staff are here to assist you with questions related to marketability, funding sources, commercial partners, patenting and other protection methods, new business start-up considerations, Mount Sinai policies and procedures, and much more. Our team approach provides you with an assigned MSIP representative supported by internal legal, financial and marketing assistance.

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 one or more commercial partners to invest.

Who is my assigned MSIP representative?

An experienced MSIP staff member is assigned to individual investigators when a technology disclosure is submitted to the office for review. Your MSIP representative will assist you in the process and manage many aspects of the review and commercialization process. If you do not have a technology disclosure to make at this time, but would like to discuss the process, please call MSIP at 646-605-7301 or email the office at technology@mssm.edu.

How can I help in this process?

- Call MSIP at 646-605-7301 or email the office at technology@mssm.edu when you believe you have created or discovered something unique with potential commercial or research value.
- Talk to a member of MSIP and complete and submit the Technology Disclosure Form (see www.ip.mountsinai.org/technology-disclosure-form) before publicly disclosing your technology or submitting a manuscript for review and publication. If a public disclosure proceeds the filing of a patent application, IP protection will be significantly diminished.
- Likewise, contact MSIP before holding any discussions with people or companies outside the Mount Sinai community to assure appropriate non-disclosure agreements are in place.

- On the Technology Disclosure Form, include companies and contacts you believe might be interested in your invention or who may have already contacted you about your work. Studies have shown that most licenses are executed with commercial entities known by the inventor, so your contacts can be extremely useful.
- Respond to MSIP and outside patent counsel requests. 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 your MSIP representative informed of upcoming publications, interactions with companies, or new research results related to your intellectual property.

What are the typical steps in the process?

Please refer to the graphic on the following page and the corresponding descriptions of each step in the process.

RESEARCH

Observations and experiments during research activities often lead to discoveries and inventions that may have commercial applicability.

DISCLOSE A TECHNOLOGY

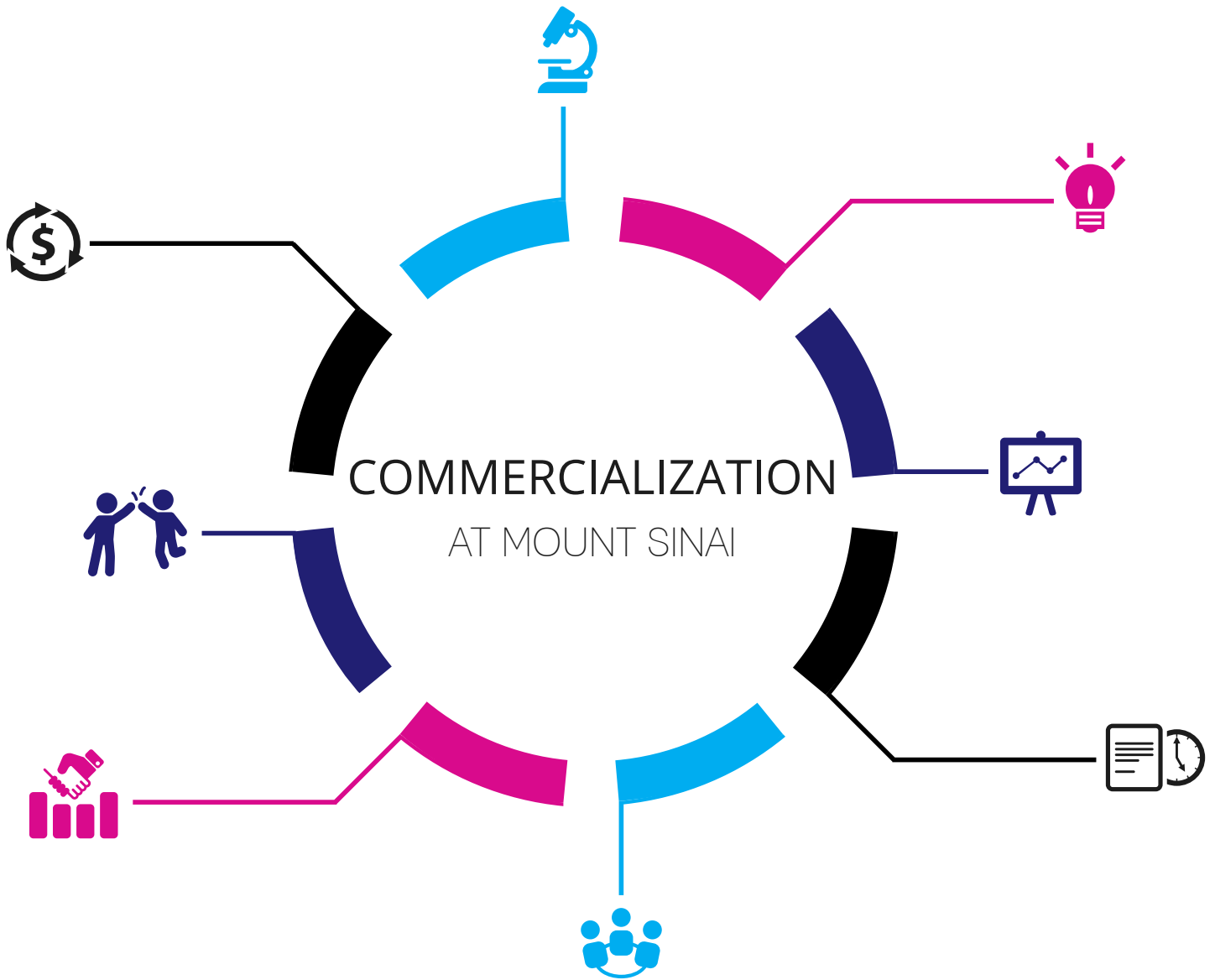
The discoveries and inventions are formally disclosed by the inventors submitting a confidential Invention Disclosure form (www.ip.mountsinai.org/technology-disclosure-form).

MARKET ASSESSMENT

MSIP assesses a disclosed invention and develops a preliminary commercialization strategy. Based on this assessment, MSIP determines whether to assert the school's rights in the disclosed invention. The assessment and determination is performed in conjunction with inventors, outside counsel, and/or advisors as appropriate.

PATENTING AND LEGAL PROTECTION

If the school's rights are asserted on an invention that appears suitable for patenting, MSIP will engage outside counsel to pursue patent protection for the invention. When appropriate, the school may utilize copyright, trade secret, or trademark rights to commercialize inventions or works of authorship.



MARKETING



MSIP proactively approaches companies, entrepreneurs, and investors who have been identified as suitable partners to bring the technology to market. MSIP also showcases available technologies online and at appropriate conferences. In addition, faculty publications, presentations, or academic know-how may result in third-party licensing interest.

NEGOTIATIONS



Marketing activities may result in one or more parties requesting an in-depth examination of the technology. This can involve signing a non-disclosure agreement and additional discussions with the inventors. Interested prospects will present a plan for commercialization and negotiate business terms with MSIP.

LICENSING



When the partners are ready to move forward, MSIP prepares legal agreements to reflect the business terms negotiated. When the agreements are signed by both parties, the startup or licensee has the right to commercialize the invention. Compensation varies and may involve fixed fees, milestone fees, royalties, equity, and other forms of consideration. Compensation is shared with inventors in accordance with policy.

COMMERCIALIZATION AND REVENUE



The path to commercialization varies depending on the nature of the invention, the market it is addressing, and the invention's stage of development. Under the terms of the agreement, the commercialization partner provides regular progress reports to the school on its commercialization activities.

RESEARCH CONSIDERATIONS

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

Yes, but since patent rights are affected by these activities, it is best to submit a Technology Disclosure (discussed in next section) well before communicating or disclosing your invention to people outside the Mount Sinai community. Once publicly disclosed (published or presented in some form), an invention will have diminished patent potential. Be sure to inform your MSIP representative of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/masters thesis, publication, company presentation 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 may influence the ownership and license rights of your subsequent research results. If you wish to obtain materials from outside collaborators, an incoming Material Transfer Agreement (MTA) should be completed. Contact your MSIP representative, or call 646-605-7301 or email us at technology@mssm.edu, to assist you in completing outgoing MTAs or Confidentiality Agreements.

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

Yes. However it is important to document items that are to be shared with others and the conditions of use. If you wish to send materials to an outside collaborator, an outgoing Material Transfer Agreement (MTA) should be completed for this purpose. It also may be necessary to have a Confidentiality Agreement completed to protect your research results or intellectual property. Contact your MSIP representative, or call 646-605-7301 or email us at technology@mssm.edu, to assist you in completing outgoing MTAs or Confidentiality Agreements.

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

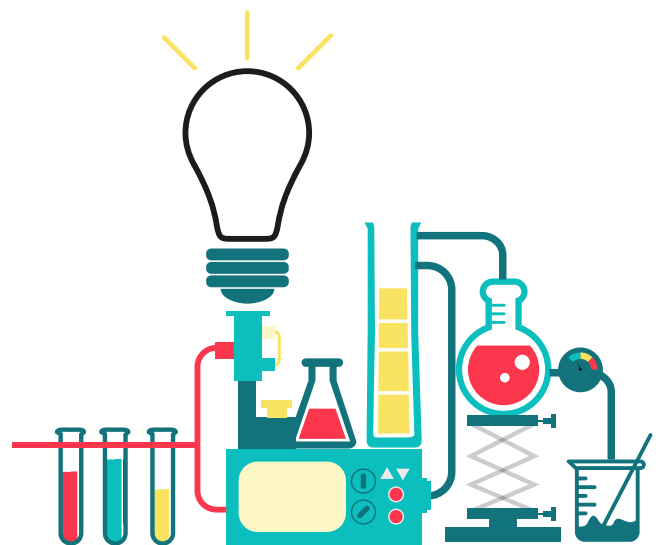
The Sponsored Research Agreement (SRA) should specify the intellectual property (IP) rights of the sponsor. Mount Sinai generally retains ownership of the patent rights and other intellectual property resulting from sponsored research. However, the sponsor may have rights to obtain a license. Often, sponsored research contracts allow the sponsor a limited time to negotiate a license for any patent or intellectual property rights developed as the result of the research. Even so, the sponsor generally will not have contractual rights to discover-

ies 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 with industry or others which require licenses to patents or other intellectual property created during the project are handled by MSIP. If you have questions about sponsored research, please contact your MSIP representative, or call 646-605-7301 or email us at technology@mssm.edu.

What about consulting?

When researchers enter into consulting agreements, they are deemed to be acting outside of the scope of their employment. Mount Sinai's Conflicts of Interest (COI) Office reviews faculty consulting agreements to assure they are consistent with institutional policies and have followed the proper Mount Sinai review and approval process. Researchers who enter into consulting agreements should familiarize themselves with Mount Sinai's policies relevant to consulting activities. The researcher is expected to ensure that the terms of the consulting arrangement are consistent with the Mount Sinai's policies, including those related to IP ownership, employment responsibilities and use of Intellectual Property. MSIP is available to provide informal advice on how your consulting agreement relates to your Mount Sinai inventions. For more information, please visit [Mount Sinai's COI Office](#).



TECHNOLOGY DISCLOSURE

What is a Technology Disclosure?

A Technology Disclosure is a written description of your invention or development that is provided to MSIP. The Technology Disclosure should list all collaborators, sources of support and ideally include all of the information necessary to begin pursuing protection, marketing, and commercialization activities.

This form (www.ip.mountsinai.org/technology-disclosure-form) will be treated as "Mount Sinai Confidential." Based on the Technology Disclosure, MSIP staff 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 with parties outside of Mount Sinai.

Why should I submit a Technology Disclosure?

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

How do I know if my discovery is an invention?

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

When should I complete a Technology Disclosure form?

You should complete a Technology Disclosure form for any potential invention made with federal funds as well as whenever you feel you have discovered something unique with possible commercial value. This should be done well before presenting the discovery through publications, poster sessions, conferences, press releases, or other communications. Once publicly disclosed (i.e., published or presented in some form), an invention will have diminished patent value. Be sure to inform your MSIP representative of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal, dissertation/masters thesis, publication, or other public presentation including the invention.

Should I disclose research reagents?

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

Should I disclose drug/therapeutic targets?

Though targets are not generally patentable, antibodies, peptides and small molecules to targets may be. You are encouraged to disclose your work on promising targets early on so a patent strategy can be considered. Answering some or all of the following questions will assist us in evaluating potential:

- Is there a model in animals or cells that causally links the target with a disease?
- Do current data suggest strongly that there is a clear and causal relationship between target and disease state?
- Has a small molecule, peptide or antibody been used to demonstrate target/disease association? If so, is the molecular interaction defined/understood?
- Is the target tractable to a small molecule, peptide or antibody: If there's a suspected protein-protein interaction, can the investigator demonstrate tractability to a small molecule, peptide or antibody?
- Absent a crystal structure: can the investigator demonstrate the lack of reactivity, i.e., the lack of time-dependent, and/or concentration dependent inhibition of target?
- Is there a discovery-quality primary assay that may be adapted for compound or antibody screening?
- Is the compound, peptide or antibody active in a cellular assay, giving credence to molecular target engagement?
- Is there a ready source of the target protein? Are clones available? Is there a cell line available?
- Is there an acute mouse or other animal model of the disease state that is tied to the target? Does a relevant biomarker exist?
- Has a hybridoma been isolated for the relevant antibody developed and is it accessible?

ASSESSMENT OF DISCLOSURES

How does Mount Sinai assess Technology Disclosures?

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

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

MSIP will work with you to develop the appropriate commercialization strategy for the invention. Some technologies lend themselves to non-exclusive licensing (licensing to multiple 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 our 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, MSIP supports Mount Sinai software developers who choose to make their work available through open source mechanisms, provided the open sourcing is consistent with obligations to sponsors, and that each developer's department supports the decision. Developers should seek authorization from an appropriate department chair or dean.

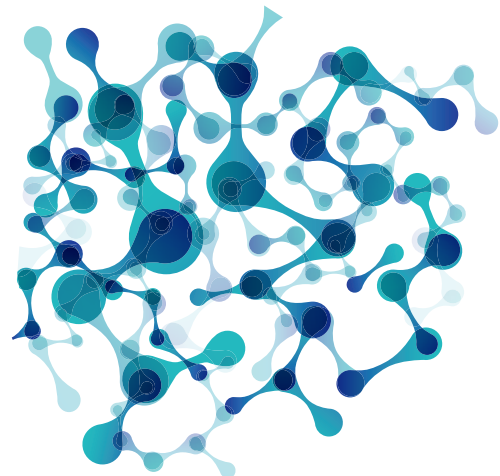
Is an invention ever assigned to an Inventor?

If MSIP decides not to pursue patent protection and/or actively market the invention, Mount Sinai may negotiate transfer ownership to the inventor(s). Reassignment of the inventions funded from U.S. government sources requires the government's prior approval.

BLUE MOUNTAIN TECHNOLOGIES

What is Blue Mountain Technologies?

Blue Mountain Technologies is an internal business unit, managed by MSIP to bring the Mount Sinai's growing portfolio of research reagents, such as antibodies, molecular diagnostics, and devices to market through commercial partnerships. If you have unique research reagents with established utility for drug discovery and development and/or clinical use, contact MSIP at 646-605-7301 or email Felipe Araujo, PhD, Director Blue Mountain Technologies at felipe.araujo@mssm.edu.



TRANSFERRING MATERIALS

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

Why are MTAs essential?

MTAs are essential to protect:

- publication rights
- intellectual property rights
- against liability to other parties

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

An MTA typically sets forth rights to use the materials and may control rights to the results or their use. Often MTAs address publication, limitations on the use of the material, and the intellectual property rights of the provider and the recipient parties in inventions arising from the use of the material.

Given that money is rarely associated with these transfers, MTAs may be perceived by some to be inconsequential transactions. However, they are binding legal agreements that can impact a researcher's current and future research.

MTAs are processed through MSIP. In order to process MTAs in a timely manner, please alert MSIP to the need for an MTA as early as possible, well before the materials are required, as MTAs may require time to negotiate.

Types of MTAs for requesting or providing materials:

1. Academic/non-profit
2. For-profit/company (usually requires more time to negotiate than an MTA with an academic/non-profit)

Under what circumstances is an MTA needed?

MTAs are required whenever a material is traveling from Mount Sinai out to another party, or traveling from another party in to Mount Sinai and the provider of the material requires the recipient to abide specific terms.

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

Among the terms that Mount Sinai will not accept are terms that:

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

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

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

Who has the authority to sign an MTA?

MTAs are legally binding agreements between Mount Sinai and the party providing or sending the material. Therefore, they must be signed by the Vice President for Technology and Business Development or their designator. It is important to be aware that the Mount Sinai faculty member sending or receiving the material is not a legal party to the MTA and the faculty member has no power to bind Mount Sinai to a legal agreement by signing that agreement. However, faculty are asked to sign MTAs as "read and acknowledged" to assure Mount Sinai that they understand the terms of the MTA and that it accurately reflects the needs of the faculty member's laboratory.

What is Mount Sinai's position on MTAs?

MSIP will prepare outgoing MTAs and review incoming MTAs as a service to the research community. MTAs are required before any material is sent or received when the sender requires the recipient to abide specific terms.

How do I work with MSIP in starting a MTA?

To expedite your MTA, visit www.ip.mountsinai.org/agreements to initiate a Quick Form.

LICENSES AND 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 Mount Sinai. Mount Sinai 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 Mount Sinai.

What is a licensee?

A company or third party with permission to use your intellectual property.

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 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 Mount Sinai to have multiple potential licensees bidding on an invention.

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

Per Mount Sinai policy, a share of any financial return from a license is provided to the inventor(s). For more information, see Section 4.19. Royalty Distribution – General under the [Policies on Intellectual Property](#): Ownership and Commercial Development). Most inventors enjoy the satisfaction of knowing their inventions are being deployed for the benefit of the public. New and enhanced relationships with businesses are another outcome that can augment one's teaching, research and consulting. In some cases, additional sponsored research may result from the licensee.

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

Many licensees require the active assistance of the inventor(s) 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 Mount Sinai. Your participation with a

start-up is governed by Mount Sinai conflict of interest policies and the approval of your supervisor.

What other types of agreements and considerations apply to tech transfer and are administered by MSIP?

- Non-Disclosure Agreements (NDAs), also known as Confidential Disclosure Agreements (CDAs), are often used to protect the confidentiality of an invention during evaluation by potential licensees. NDAs also protect proprietary information of third parties that Mount Sinai researchers need to review in order to conduct research or evaluate research opportunities. MSIP enters into NDAs for Mount Sinai proprietary information shared with someone outside of Mount Sinai.
- Material Transfer Agreements (MTAs), used for incoming and outgoing materials at Mount Sinai are administered by MSIP. These agreements describe the terms under which Mount Sinai researchers and outside researchers may share materials, typically for research or evaluation purposes.
- 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 Mount Sinai preserves the opportunity for a third party to negotiate a license for intellectual property. Option clauses are often provided in a Sponsored Research Agreement to corporate research sponsors or Option Agreements are entered into with third parties wishing to evaluate the technology prior to entering into a full license agreement.
- Sponsored Research Agreements (SRAs) describe the terms under which sponsors provide research support to Mount Sinai. Industry SRAs are negotiated by MSIP in cooperation with the Grants and Contracts Office.

Where can I find Quick Forms to start the process of negotiating an agreement through MSIP?

- To expedite the agreement process, MSIP has implemented Quick Forms that can be found online at www.ip.mountsinai.org/agreements.

FINDING A LICENSEE

How does MSIP market my inventions?

MSIP staff use various resources and strategies to identify potential licensees and market inventions. Sometimes existing relationships of the inventors, MSIP staff, and other researchers are useful in marketing an invention. Market research can assist in identifying prospective licensees. We also examine other complementary technologies and agreements to assist our efforts. We use our 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 many licensees were already known to the inventors. Thus research and consulting relationships are often a valuable source for identifying licensees. Licensees are also identified through existing relationships of MSIP staff. Our licensees often license more than one technology from Mount Sinai. 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 Mount Sinai inventions tend to be in the early stage in the development cycle and thus require substantial commercialization investment, making it challenging 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 often 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 OTBD staff 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. However, for some technologies a worldwide exclusive license is needed to create the incentive for a company to invest in commercialization.

There are over **XX products** on the market or in clinical development based on **Mount Sinai discoveries**, examples include:



MORE ON COMMERCIALIZATION

What activities occur during commercialization?

Most licensees continue to develop an invention to enhance the technology, reduce risk, prove safety and efficacy, and satisfy the market requirements for adoption by customers. This can involve additional testing, regulatory approval, prototyping for manufacturability, durability and integrity, further development to improve performance and other characteristics, and 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 may be as a scientific advisor or more, and can vary depending on your interest, in the interest of the licensee in utilizing your services, and any contractual obligations related to the license or any personal agreements.

What revenues are generated for Mount Sinai if commercialization is successful? 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?

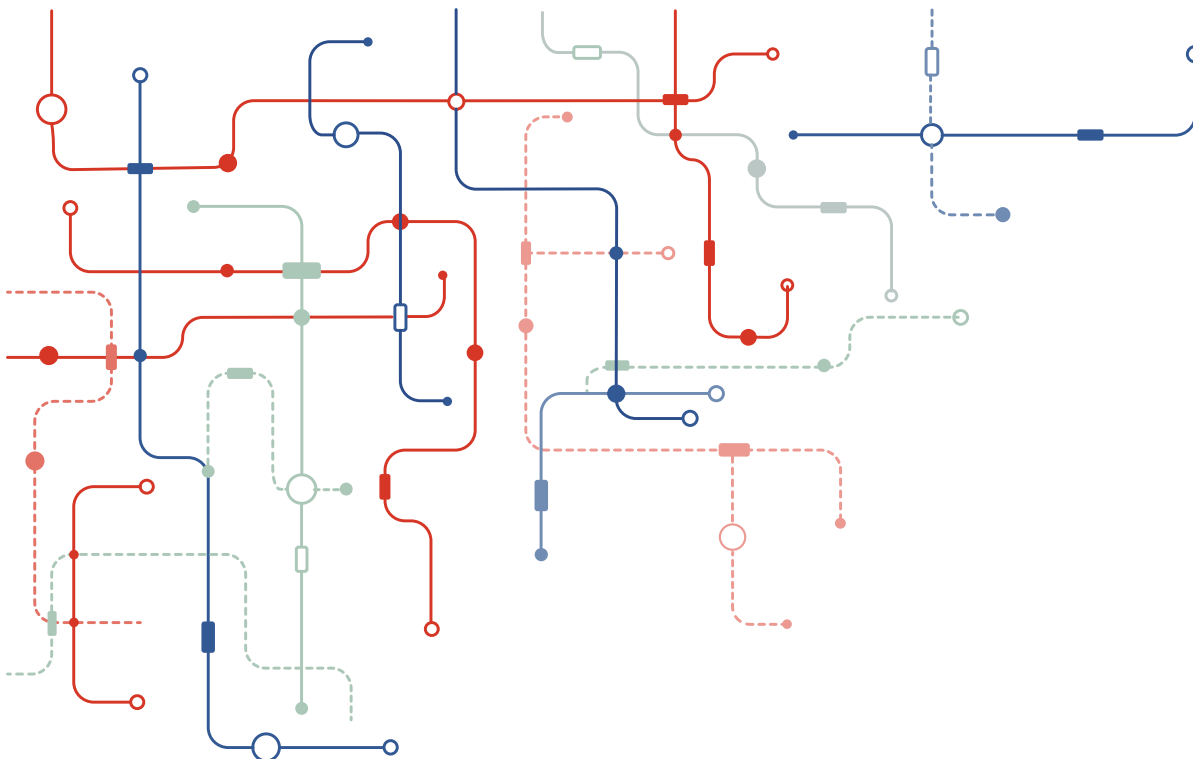
Most licenses have licensing fees that can be very modest (for start-ups or situations in which the value of the license is deemed to warrant a modest license fee) or can reach hun-

dreds 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. For more information, see Sections 4.19. Royalty Distribution – General and 4.20. Equity Distribution under the [Policies on Intellectual Property: Ownership and Commercial Development](#))

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

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

*Abrams, I., Leung, G., Stevens, A.J. (2009). How are U.S. Technology Transfer Offices Tasked and Motivated – Is it all About the Money? Research Management Review, Volume 17, Issue 1 Fall/Winter.



REVENUE AND DISTRIBUTION

How are license revenues distributed?

MSIP is responsible for managing the expenses and revenues associated with technology agreements. Per the Mount Sinai Policy, revenues from license fees, royalties and equity—minus any unreimbursed patenting and legal or other out of pocket expenses—are shared with inventors. For more information, see Section 4.19 Royalty Distribution under the [Policies on Intellectual Property](#): Ownership and Commercial Development.

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

License revenues are typically reported as income on Tax Form 1099. 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 Mount Sinai. To avoid potential tax liability, revenues waived by you to your department/institute must not be under your control.

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

In cases where a license involves a patent with multiple inventors and/or involves multiple patents, MSIP will request the inventors to decide, from their perspective, a fair and equitable distribution of the inventors' income. If the inventors can achieve an agreement, they will submit a letter signed by each one of them to MSIP stating their agreement and providing the specific income distribution scheme.

In the event that such agreement cannot be achieved, any one or more of the Inventors can notify MSIP, who will then request the Dean to form a committee of the faculty to make an appropriate recommendation with input from MSIP which with the Dean's approval will be binding on the inventors. For more information, see 4.21. Royalties - Special Cases under the [Policies on Intellectual Property](#): Ownership and Commercial Development).

What is equity?

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

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

Under Mount Sinai Conflicts of Interest Policy, inventors who

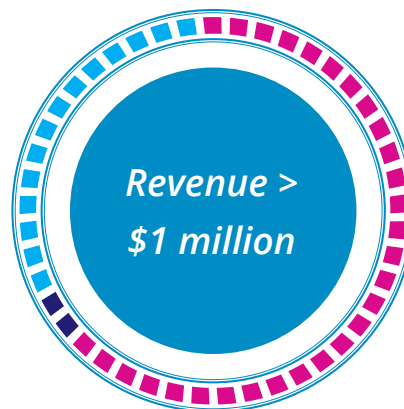
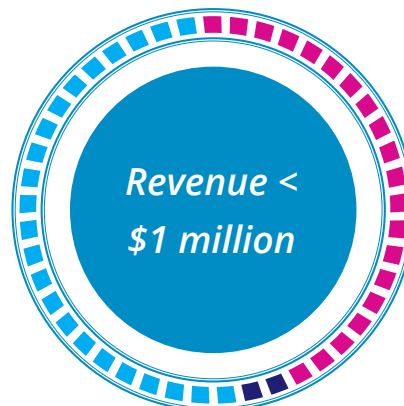
receive equity from a licensee are required to report such holdings on their annual Report of Relationships of Outside Entities form. For more information, contact Kenneth Brower, Director of the Conflicts of Interest Office at kenneth.brower@mssm.edu.

How is equity from a license distributed?

Per the Mount Sinai Policy, returns from equity obtained as part of a license agreement are shared with the inventors.

For more information and a breakdown of distribution percentages, see 4.20. Equity Distribution under the [Policies on Intellectual Property](#): Ownership and Commercial Development).

Licensing Revenue* Distributions:



Legend:
Mount Sinai | Inventor(s) | Inventor(s) Dept./Institute

*Adjusted royalty income = gross income less Mount Sinai out-of-pocket expenses specific to the licensed technology

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 may be 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; and
- potential revenues sufficient to sustain and grow a company.

MSIP 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 MSIP and the inventors. If a new business start-up is chosen as the preferred commercialization path, MSIP staff will assist you in planning and executing the process and providing hands-on assistance and access to Mount Sinai and outside resources.

What assistance and resources are available to the inventor?

MSIP staff activities may include locating prospective management talent, developing a funding strategy, making introductions to probable investors, reviewing business plans, and engaging experts to work on key gating issues.

What role does an inventor usually play in a company?

Mount Sinai faculty typically serve as technology consultants or scientific advisors. In many cases, the faculty role is suggested by the start-up investors and management team who work with the inventors to 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 in a start-up is subject to Mount Sinai's Conflict of Interest Policy.

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 may 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 Mount Sinai processes such as conflict of interest reviews.

Can Mount Sinai accept equity in the company?

Mount Sinai 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 Mount Sinai to share some of the risk associated with the start-ups. A decision to take equity must make sense for both Mount Sinai and the company.

Will Mount Sinai pay for incorporating a start-up company?

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 Mount Sinai counsel, though it is advisable and recommended that the corporate IP Counsel and MSIP staff 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.

NAVIGATING CONFLICT OF INTEREST

How does Mount Sinai define a conflict of interest?

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

When should I seek guidance on conflict of interest?

Whenever a question or uncertainty arises, you should seek guidance from Mount Sinai's Conflicts of Interest (COI) Office (Kenneth Brower, kenneth.brower@mssm.edu) for research-related issues and/or your MSIP representative for license-related issues. You can also call the COI Helpline at 212-241-0845. There are two times in particular when input is valuable: when research proposals are submitted to Mount Sinai's Grants and Contracts Office (GCO; grants@mssm.edu; 212-824-8300); and when a license, option or MTA is being considered with a company in which the faculty member, or any Mount Sinai employee, has an equity or management interest.

What kinds of issues concern conflict of interest reviewers?

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

What are examples of a conflict of commitment?

A conflict of commitment may arise if duties, assignments or responsibilities associated with a technology license or outside business arrangement (e.g., consulting) have a negative impact on your ability to meet commitments associated with your Mount Sinai employment or exceed the amount of allowable time for these activities. The best approach is to fully disclose your proposed arrangement to your supervisor and discuss the implications for your job responsibilities.

How does Mount Sinai manage possible conflicts of interest associated with research and tech transfer transactions?

MSIP representatives can advise you on conflict of interest issues or direct you to the appropriate COI staff member. It is the responsibility of the researcher or faculty member to disclose and document any outside arrangements as described in Mount Sinai's Conflict of Interest Policies. There are two types of on-line forms for reporting financial interests: the annual Report of Relationships with Outside Entities and the research study-specific Financial Conflicts of Interest in Research Disclosure Form. The annual forms are reviewed by the Conflicts of Interest Officer within the Dean's Office. Research disclosure forms are reviewed by Mount Sinai's Financial Conflict of Interest in Research Committee to determine if a conflict of interest exists and whether it needs to be managed, reduced or eliminated.

For more information on the review and management of conflicts of interest relating to research, see the [Policy on Financial Conflicts of Interest in Research](#).

COMMON ACRONYMS

CDA: Confidential Disclosure Agreement

COI: Conflicts of Interest

GCO: Grants & Contracts Office

IIA: Inter-Institutional Agreement

IP: Intellectual Property

MTA: Material Transfer Agreement

NDA: Non-Disclosure Agreement

MSIP: Mount Sinai Innovation Partners

PCT: Patent Cooperation Treaty

SRA: Sponsored Research Agreement

USPTO: United States Patent & Trademark Office



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