
GUIDE TO TECHNOLOGY TRANSFER

Research Foundation for Mental Hygiene, Inc.

“The Congress shall have the power – to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”

United States Constitution
Article 1, Section 8

Guide to Technology Transfer

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Introduction

Issues involving the protection of intellectual property and the transfer or licensing of intellectual property to industry are quite complex. This publication provides a brief overview of the technology transfer process and how intellectual property is managed by the Research Foundation for Mental Hygiene, Inc. (RFMH). This manual is intended as an informational guide for researchers, staff and administrators to help them understand the issues associated with protection of intellectual property, inventor obligations and rights under RFMH policies and the procedures that implement these policies.

What is technology transfer?

Technology transfer is the process by which scientific knowledge, materials or technical capabilities developed through sponsored research are transferred to commercial enterprises for the purpose of further development and commercialization. Examples of technologies include: patent inventions, software, research tools and reagents, diagnostic assays, therapeutic compounds, vaccines, educational materials, etc. Although this process can be very complex, it basically involves technical knowledge, a user (e.g., a biotech company) and an interface connecting the two (e.g., RFMH).

The Bayh-Dole Act, also known as the Patent and Trademark Act of 1980, is the legal frame work through which inventions and technologies developed at nonprofit institutions using funding from the federal government are transferred or licensed to commercial enterprises. The Bayh-Dole Act encourages dissemination of research results by allowing universities and public research institutes to own and manage inventions derived from government-funded research. The Bayh-Dole Act also provides an incentive for nonprofit institutions to protect their inventions, which in turn, has encouraged industry to increase sponsorship of university research. Since passage of the Bayh-Dole Act, the number of patents obtained by universities has increase about 1520%, while industry funds invested in university research has increased 320%¹.

What is intellectual property?

Intellectual property is any product of the creative intellect that has value in the market place. Examples of intellectual property include: ideas, inventions, literary works, songs, unique names, business methods, computer programs, industrial processes and chemical formulas. Legal protection for intellectual property may take four forms:

1. **Patent** – a patent is a grant of the right to exclude others from making, using, offering for sale, selling or importing the patented invention for a specific period of term (typically twenty years). A patent grants a limited monopoly which allows the inventor(s) to recoup the costs of research and development. Any idea, process, machine, article of manufacture, or composition of matter that is useful, novel and non-obvious can be patented. There are three types of patents: utility, design and plant. Utility patents are

¹ AUTM U.S. Licensing Survey, FY 2004 Survey Summary, editors Ashley J. Stevens, Frances Toneguzzo and Dana Bostrom.

the primary type of patents and provide protection for the function of an invention. Most inventions in the field of biomedical research are covered by utility patents. Design patents protect the aesthetic aspects or design of an invention but not its function. Plant patents cover new varieties of plants.

2. **Copyright** – a copyright protects original work of expression fixed in a tangible form including, literary, musical, pictorial, graphic, sculptural and audiovisual works. A copyright protects the expression of the idea but not the idea itself. A copyright gives the owner of the copyright the exclusive right to reproduce the copyrighted work, to publicly perform the copyrighted work or to publicly display the copyrighted work. The term of a copyright is 95 years from the date of publication or 120 years from the time the work was created or the life of the author plus 70 years.
3. **Trademark** – a trademark is anything that identifies the source of goods or services and distinguishes them from the goods and services of another. Trademarks may include words, symbols, numerals and letters, pictorial presentations, designs, colors, sounds, scents, domain names and the shape of a container or package. Trademarks may be used to prevent others from using a confusingly similar mark, but not to prevent others from making the same goods or from selling the same goods or services under a clearly different mark.
4. **Trade secret** – a trade secret is confidential or secret information used to gain a business advantage over others who lack the information. A trade secret may comprise a formula, pattern, device, or indeed any information that may be used to gain such an advantage. A trade secret may be enforced indefinitely provided that the subject information does not become publicly available. Trade secrets protect ideas or materials – but only by preserving their secrecy. The owner of a trade secret has rights only against either those who have agreed not to disclose the secret information or those who have obtained the secret information by misappropriation. All others (even competitors) who innocently gain access to the information can benefit from using the trade secret information in any way they wish.

What is an invention?

An invention involves both conception (idea) and reduction of the idea to practice. In other words, an invention is an idea and some indication that the idea will actually work. There are two ways to reduce an invention to practice:

1. **Actual** – an example of actual reduction to practice is a working model demonstrating that the invention will work as intended.
2. **Constructive** – constructive reduction to practice is the act of filing a patent application even though an invention is not yet physically reduced to practice or “made”. The summary and illustrations of the patent application must allow a person with ordinary knowledge of the field to make and use the invention (reduce the invention to actual practice) without undo research or experimentation.

What is a patentable invention?

One of the first steps in the process of technology transfer is to recognize patentable inventions. The Supreme Court has ruled that patents cover “anything under the sun that is made by man”². Patents are granted for processes, machines, articles of manufacture, compositions of matter or new and useful improvements thereof. A process encompasses a new use of a known process, machine, article of manufacture or composition of matter. Manufacture refers to the production of articles from raw or prepared materials. Compositions of matter are physical entities and chemically-combined substances. Laws of nature, physical phenomena and abstract ideas are not patentable. They are “the basic tools of scientific and technological work and therefore are free to all men and reserved exclusively to none”³.

In order to be patentable, an invention must possess three qualities:

1. **Utility** – the invention must be useful.
2. **Novelty** – the invention must be new and novel. The invention cannot be disclosed in the prior art.
3. **Non-obvious** – the invention must be more than just an obvious extension of existing technology for a person of ordinary skill in the field of the invention.

What is a public disclosure?

If the invention is publicly known, used, described or patented prior to its invention by the inventors, the invention is considered unpatentable due to lack of novelty. This is very important. **There are situations where inventors can inadvertently render their own invention unpatentable.** These activities are common in academic research and include:

- Publishing a scientific paper;
- Making an oral presentation at a seminar or scientific meeting;
- Presenting a poster at a scientific meeting;
- Writing a grant application (once funded, grants are subject to public disclosure through the Freedom of Information Act); and
- Distributing a prototype or samples (even to other researchers).

These activities result in the loss of patent rights.

What should you do when an invention occurs?

DISCLOSE! The first step is to disclose your invention to the Institute Director or the Deputy Director of Administration and the RFMH central office. The RFMH has prepared an Invention Disclosure Report for the purpose of disclosing inventions. The Invention Disclosure Report requires a description of the invention. A draft manuscript which describes the invention

² Diamond v. Chakrabarty, 447 US 303 (1980).

³ Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 US 127 (1948).

if often helpful. The form also requires information on publications, public disclosures, prior art, research sponsors, as well as administrative information (inventor names(s), phone number(s), institution(s), etc.). The Invention Disclosure Report, signed by all inventors, should be forwarded to the Institute Director or Deputy Director of Institute Administration and the Technology Transfer Associate at the RFMH central office.

What happens after an invention is disclosed?

An initial review of the invention for patentability and market potential is conducted, as well as a search of the relevant prior art, by the RFMH. Based on the results of the legal and market reviews, the RFMH decides whether to seek patent protection for the invention in question. Patentable invention are referred to a patent attorney, who begins the process of patent prosecution by preparing a draft patent application.

Who is an inventor?

In a collaborative research endeavor with several scientists involved, as well as laboratory technicians and graduate students, it is not surprising that the question of who is an inventor frequently arises. An inventor is the person(s) who conceives of the idea and reduces the idea to practice.

U.S. Patent Law requires that all inventors be correctly named in a patent application. The patent is considered invalid if the inventors are not properly listed, e.g. non-inventor named as an inventor or inventor left off patent. To be an inventor, one must have made an inventive contribution to the subject matter of at least one claim of the patent. Merely carrying out the details of another's conception by utilizing standard techniques or by following the instructions of another does not make someone an inventor.

Authors are not necessarily inventors. Academic scientists tend to err on the side of inclusion in writing research papers, naming as authors both cognitive and technical contributors to the work, as well as trainees. For the purposes of filing a patent application, **only ideas count towards determining inventorship.**

What is the inventors' role in technology transfer?

The inventors play a central role in the technology transfer process. The inventors are the individuals most familiar with the technology and the strongest advocate of the technology. The inventors have a number of important responsibilities:

1. **Document** – U.S. patent law grants a patent to the first person to invent. The inventors must be able to document that they were the first to invent. Some keys to keeping good notes include:
 - Keep notes in a bound notebook;
 - Make daily entries in pen of ideas, work done and laboratory data collected – date and sign your entries; and

- Have “significant” entries signed by someone who has witnessed the work and understands it, but has not participated in it.
2. **Disclose** – the single most important responsibility of the inventors is to disclose the invention to the proper authorities, the Institute Director or Deputy Director of Institute Administration and the RFMH central office (see p. 8, Where do I go for help?). Fill out an official Invention Disclosure Report to disclose an invention. Inventions must be disclosed as soon as possible after they are conceived. The longer you wait to disclose an invention the more difficult it is to protect the invention and prevent public disclosure.
 3. **Prevent public disclosure** – public disclosure of an invention prior to filing a patent application results in loss of patent rights (see page 3, What is a public disclosure?). It is the inventors’ duty to limit oral and written disclosures of the invention until a patent application is filed.
 4. **Assist** – the inventors work closely with the patent attorney to prepare the patent application. The inventors are familiar with the technical aspects of the invention and the prior art of the field. Therefore, it is very important that each inventor review the patent application to ensure that the application is factually correct, complete and fully discloses the invention.
 5. **Assign** – all inventors shall assign and transfer to the RFMH all right, title and interest to all invention and patents conceived for first reduce to practice with the support, in whole or in part, of sponsored research funds.

What is the role of the RFMH?

All matters related to discoveries and inventions arising from sponsored research are coordinated by the RFMH. The duties of the RFMH include:

1. **Identify** – the RFMH solicits invention disclosures for new discoveries and technologies.
2. **Evaluate** – the RFMH conducts an initial legal, scientific and market potential review of all disclosed intellectual property.
3. **Market** – the RFMH forms commercialization strategies and markets intellectual property to potential licensees. The RFMH uses a variety of techniques to identify commercial partners willing to license the technology and share patent costs.
4. **Negotiate** – the RFMH negotiates, executes and manages licensing, research and other agreement pertaining to intellectual property developed with sponsored research support.
5. **Administer** – the RFMH oversees all aspects of the technology transfer process, ensures timely handling of intellectual property issues, retains patent attorneys to prosecute patent applications, maintains records and an account of moneys spent and received.

6. **Educate** – the RFMH educates and advises administration and researchers on the commercialization process.

Who owns the intellectual property?

Inventions and technology developed in the course of sponsored research are technically owned by the sponsor. The Bayh-Dole Act allows the grant recipient, the RFMH, to obtain title to inventions developed under federal funding agreements. Private sponsors typically have similar policies regarding inventions. These terms are spelled out in the sponsored research agreement. Adherence to these sponsor provisions is necessary in order for the RFMH to comply with federal and state laws and meet contractual obligations. As a condition of employment or as a condition of the RFMH agreeing to administer a sponsored funded research project, employees and Principal Investigators must agree to:

- Reveal applications or patents in which they are listed as an inventor;
- Submit an Invention Disclosure Form immediately following the conception or first reduction to practice of any discovery, invention or improvement on an existing invention;
- Assign to the RFMH all rights in discoveries, inventions and invention improvements, conceived or first reduced to practice through use of sponsored research funds; and
- Do whatever is required, at no personal cost or expense, to enable the RFMH to obtain, maintain and defend patents in which you are an inventor.

These obligations extend to work performed on all sponsor funded research, regardless of the party to which inventions are assigned in the research agreement. Certain responsibilities will continue after termination of employment or after a Principal Investigator no longer has a grant administered by the RFMH. Employees or Principal Investigators who have supervisory responsibility for a laboratory or program will be responsible for seeing that those under their supervision are aware of their obligations and that they are carried out in accordance with RFMH policy.

What about the sponsor?

The federal government under the Bayh-Dole Act allows the grant recipient (RFMH) to retain title and ownership of any invention developed in whole or in part with the use of federal funds. Retention of title is subject to reporting requirements and the granting of a royalty-free license to the government to use the invention for its own purposes.

Some private sponsors of research have policies requiring that the title to invention be assigned to the sponsor or that royalty income be shared with the sponsor. These policies are referenced on the grant application form or in the award acceptance form, and signing the application or acceptance of the award signifies agreement with the sponsor's policy. This is one of reason why it is important to have proper institutional review of applications and contracts.

What are Material Transfer Agreements?

During the course of research, scientists may develop a variety of tangible, research materials, including clones, vectors, transgenic mice and hybridomas. These materials are not typically patented but may be licensed to commercial partners. Please see Biological Material Disclosure Form. Research materials or tools are commonly shared with other researchers. In fact, the terms of research projects sponsored by the federal government require that research tools developed with grant funding be made available to the scientific community. Material Transfer Agreements are contracts governing the transfer of tangible materials between organizations. Material Transfer Agreements typically prohibit the use of research materials for commercial purposes and formally establish that the materials are being used for non-commercial, research purposes. Failure to use a Material Transfer Agreement may result in loss of control or ownership of the material. The RFMH has developed a simple, standard Material Transfer Agreement which must be used when distributing research materials.

Outside researchers supplying materials may request that a Material Transfer Agreement be signed prior to providing the materials. These Material Transfer Agreements may include restrictive clauses that affect publication and future patent rights. In some extreme examples of abuse, investigators were prevented from publishing results or were sued for violating restrictive clauses that granted total control of the right to publish and commercially develop inventions arising from their research to the donor of the material. Individual investigators do not have the authority to sign Material Transfer Agreements. Material Transfer Agreements from outside organizations must be submitted to the RFMH central office for review and signature. In most cases, Material Transfer Agreement can be reviewed and implemented with minimal delay.

What are research agreements?

Commercial companies often tap the technical expertise of scientists. Activities conducted by scientists with the support of commercial entities include sponsored research, product development or evaluation, product field testing, etc. Companies will often say, “we don’t need to bother with a research agreement. A formal agreement is not necessary and will only hold up the research.” Despite these assurances, it is very important that a research agreement is negotiated. Research agreements negotiated by RFMH are designed to protect the Institute and scientists. The main intent of the RFMH’s research agreement is to protect the right of the scientists to publisher their work. Another vital part of the research agreement specifies how intellectual property will be managed. Typically, the sponsoring company will be given the option to license technology created through sponsored research. There have been instances of scientists operating without research agreement who have lost control of their data and intellectual property. All proposals by commercial entities to conduct research must be reviewed by RFMH.

What about royalties?

Most nonprofit institutions do not actually produce or sell products derived from the inventions created by their employees, instead they enter into a licensing agreement with a

company. The company licenses the right to manufacture and sell the invention and agrees to share a portion of the future revenue generated by the invention. A royalty is a portion the revenue paid back to a patent holder by a licensee in exchange for the rights to the invention. The RFMH intends to share net royalties with individual inventors. Net royalties refers to the total or gross royalties minus allowable costs, such as costs associated with patent prosecution. Thus, commercially successful invention may provide a source of income for both the Institute and individual inventors.

Where do I go for help?

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Conclusion

The ultimate goal of the RFMH's technology transfer activities is to disseminate the benefits of sponsored research to the public. Often, this involves licensing inventions to the commercial sector. This guide is intended for your information and to help you understand some of the intricacies of technology transfer. It is not intended to make you an expert on intellectual property and the patentability of inventions. Any potential invention should be disclosed, so that it can be reviewed by those skilled in determining its patentability and commercial potential. Finally, technology transfer is a cooperative process. As your partner, we at the RFMH look forward to working with you to develop the full potential of your invention.

Glossary

Bayh-Dole Act – (Pub. L. 96-517) the Patent and Trademark Act of 1980 is the legal frame work through which invention and technologies developed at nonprofit institutions using funding from the federal government are transferred to commercial enterprises.

Copyright – legal protection of an original work of expression set down in fixed form or medium (e.g., written texts, software, visual and audio materials). A copyright protects the embodiment of an idea but not the idea itself.

Disclosure – a formal document, signed by the inventor(s) and witnessed, which describes an invention in sufficient detail to enable a technical and legal evaluation of the invention.

Intellectual property – any product of the creative intellect that has value in the market place embodied in the form of patents, copyrights, trademarks and trade secrets.

Invention – a new and useful process, machine, article of manufacture, composition of matter or a new useful improvement upon them.

Inventor – individual who conceives of and reduces to practice an invention.

License – legal permission from patent owner to practice (manufacture, sell or use) an invention.

Material Transfer Agreement – an agreement governing the transfer of tangible research materials (e.g., clones, antibodies, transgenic mice, etc.). These agreements prohibit commercial use of the materials.

Patent – a grant of property right by the U.S. government to the inventor giving the owner of the patent the right to exclude other from making, using, offering for sale or selling the invention in the U.S. or importing it to this country.

Patentable invention – an invention that is useful, novel and non-obvious.

Prior art – the body of existing technology and knowledge (patents, publications, etc.) in the field of an invention.

Public disclosure – an unrestricted disclosure not bound by confidentiality obligations. Public disclosure may be oral or written.

Research agreement – an agreement governing sponsored research.

Royalty – a monetary payment to the owner of the rights to a technology as a consideration for granting to another the right to make, sell or use the technology.

Technology transfer – common term for the entire process of licensing and acquiring the rights to technologies.

Trademark – anything that identifies the source of goods or services and distinguishes them from the goods and services of another, i.e., brand name.

Trade secret – confidential or secret information used to gain a business advantage over others who lack the information.