

## Inventions

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### What is an Invention?

Generally, a patentable discovery, or invention, must be something new, not obvious, and unique. Reportable inventions can include compositions of matter, devices, and methodologies. Reportable inventions also include unique biological materials with commercial applications such as transgenic mice and cell lines. Formal patentability assessments of your inventions will be performed by TTM in conjunction with patent attorneys.

An invention is any new and useful discovery. Inventions are protected through the United States patent system as a *property right* established by the U.S. Constitution. Other countries also have their own version of our U.S. patent system. The patent system allows an inventor to obtain protection for their invention, which gives the inventor the right to prevent others from making, using or selling their invention for a period of time. The patent system grants this protective right to any invention that is a *new and useful process, machine, manufacture, or composition of matter*. Therefore, patent protection can be obtained for inventions covering, but not limited to: methods of making or doing a *thing* (e.g., method of treating a disease or conducting a surgical technique); the thing being made (e.g., a medical device, chemical or biological composition, a modified organism or plant); and improvements to already existing *processes, machines, manufactures, or compositions of matter*.

It is the policy and objective of Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development ([35 U.S.C. §200](#)). Therefore, obtaining patent protection for NIH inventions facilitates commercial development of new, novel products and services that benefit public health. Further, commercial partners who license NIH inventions also acquire the patent system's protections (i.e., the right to exclude other from making, using or selling), allowing the investment of capital and resources into development and commercialization with lower

risk.

## When Should I Report an Invention?

Timely reporting of inventions is critical because either failing to report your discovery prior to public disclosure, or submitting your [Employee Invention Report \(EIR\)](#) at the last minute or immediately before disclosure may result in loss of important patent property rights that could prevent your invention from being developed and used to benefit the public.

In general, a “public disclosure” is the release of information about the discovery in sufficient detail to allow a fellow scientist in the field to make, use, or apply the invention to their research.

Public disclosures include:

- Talks, presentations, seminars, posters
- Publications, including abstracts on websites
- Internet postings
- Graduate student theses, job interviews
- Discussions with non-NIH personnel without a [Confidential Disclosure Agreement \(CDA\)](#) in place

## Why I Should Report My Discoveries

As an NIH scientist, you must report new inventions, including improvements of previously reported inventions, to the Technology Transfer Manager assigned to your Laboratory. If you do not know the name of your TTM, please [call](#) or [email the Technology Transfer Center \(link sends e-mail\)](#).

All NIH scientists are required to promptly report their inventions by completing and submitting an EIR to their Institute's technology transfer office, before any public disclosure of the invention (i.e. manuscript/abstract publication, oral meeting presentation). The EIR allows the inventor(s) to document the invention in sufficient detail so that their technology transfer office can evaluate whether patent protection can or should be obtained.

NCI's Technology Transfer Center (TTC) has a formal [EIR review process](#), wherein TTC staff review the invention description for patentability and commercial marketability. TTC then makes a recommendation (supported by evidence and documentation) to the NIH Institute providing the EIR on whether patent protection should be pursued based on the invention's patentability and commercial viability. Using this recommendation, the NIH Institute makes a decision on whether to file a patent application.

Upon receiving the NIH Institute's decision to pursue patent protection, TTC will instruct one of our contract law firms (see below) to prepare and file a patent application with the U.S. Patent and Trademark Office (USPTO). The TTC is responsible for the supervision of both the patent prosecution process and our contract law firms to ensure that our applications have the best chance of being issued. The TTC works closely with the [NIH Intramural Research Program \(IRP\)](#) to ensure that its scientific discoveries are either

transferred to the marketplace through patenting, co-development and/or out-licensing, or published to facilitate public access.

**Please don't hesitate to contact the TTC should you have any questions.**

## **Working with TTC**

Technology transfer is the primary mechanism by which NIH research is translated into products, such as therapeutics, vaccines, diagnostics, or tools to enhance research efforts. For over 25 years, patenting and licensing for NIH was conducted centrally in the NIH Office of Technology Transfer (OTT). On October 1, 2015 these patenting and licensing functions were decentralized to nine offices of technology development embedded in the NIH institute[1]. This change provides the opportunity to align more closely technology transfer with laboratory and program goals.

There are many ways that inventors may contribute to the development and commercialization of their inventions:

- Contact your technology transfer office whenever you have a potentially patentable invention to determine whether you should file an Employee Invention Report (EIR). It is important to make this contact **before** you publish, give a talk or publicly disclose research results that might fall into this category (otherwise potential intellectual property rights can be lost).
- Provide updates whenever new research results in your laboratory impact the commercial applications of your inventions. Your research results may provide additional proof-of-concept for marketing your invention to companies in the field.
- Share the deep expertise you have in your field to support efforts to license your invention. Inventors can help by reviewing information supporting the commercial development of their technologies by a prospective licensee (e.g., scientific personnel at a company; commercial development plans; proposed developmental timelines; or details regarding the scaling up and production of GMP materials). You may be asked about costs for creating and maintaining biological materials in your lab, and relative levels of input from collaborators of jointly owned inventions.
- Avoid potential conflicts of interest by directing questions about the financial terms of licenses to your technology transfer office. As an inventor you will receive a share of royalties from licensing of your inventions. Therefore, you should never be involved in the negotiation of financial terms of a license. Should a prospective licensee attempt to involve you, please direct them to technology transfer.
- Keep NIH informed of your contact and banking information for royalty payments from licensed inventions. Information is posted at <http://www.ott.nih.gov/information-nih-cdc-and-fda-inventors> on when royalty payments are made, how to update banking information, tax statements, and payments to estates of deceased inventors.

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[1] Technology transfer offices within nine Institutes are providing patenting and licensing services for all of NIH's Institutes and Centers. [The NCI TTC serves NCI as well as nine other Institutes and Centers.](#) Contact information for other Institutes and Centers is

posted at <https://www.ott.nih.gov/technology-development-coordinators>.

## Guidance for NIH Researchers and Inventors

As a inventor in the NIH, there are several key points you need to know:

- **Record keeping:** before submitting an EIR form, it is important to maintain your laboratory records documenting the conception of your invention and what you have done to reduce it to practice. Laboratory records can be used to prove inventorship. Sometimes, such records may also be required for FDA regulatory affairs. For details, please see [Guide for Keeping Laboratory Records](#).
- **Inventor's assistance in patent process:** when a decision of filing a patent application on your invention is made, you need to assist patent attorney at contract law firm with patent filing preparation and occasionally patent prosecution. During this patent process, inventors have a duty of disclosure to disclose to USPTO all information known to them to be material to the patentability of such invention (37 CFR 1.56).
- **Inventor's assistance in licensing agreement process:** inventor's input may be also required for the process of licensing an invention to a commercial entity.
- **Invention update:** if inventors make additional development of their technology being patented during the patent prosecution, it is important to keep NCI TTC informed of all new developments of such invention. In addition, there are times that a decision of no patent filing is made on invention because it is at very early stage of development and experimental data is not sufficient to support patent claims. In this situation, the already filed EIR can serve a purpose of documenting the stage of invention development; and therefore, an updated EIR will be required to be submitted when further development strongly supports the filing of a patent application.
- **Inventor Royalties:** NIH inventions are available for licensing. Inventors receive royalties on patented invention or patent application when an invention is licensed to an outside organization. The distribution of NIH license royalties is calculated by a standard NIH formula. No NIH inventor may receive more than \$150,000 total in royalty income in a given year. Amounts in excess of this cap are distributed to co-inventors (unless they also cap, in which case the royalties flow back to the Institute or Center). Even if inventors leave government employment, they are still entitled to your royalty share. If you have questions, please [contact us \(link sends e-mail\)](#) or contact your royalty coordinator (see below). For additional details, please visit [Information for Inventors / Royalty](#).

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### **When I Leave NIH**

There are certain technology transfer obligations that must be clarified with NCI TTC when NCI inventors are departing from NCI. There are several key points to keep in mind and clarify with NCI TTC:

- Invention reporting: you must assure you have reported any invention of discovery while at NCI prior to departure.
- Continued assistance in patent process: if you have been named on as an inventor on any patent application or patent during your employment at NCI you will be expected to provide ongoing assistance related to filed patents (signing assignments, assistance with responses to PTO etc.).

Update of Address: you need keep NCI updated on any change of address in the future. Instructions for inventors in providing banking and contact information are addressed in an OFM narrative on the NIH Royalty Program. You are also expected to provide the NIH with any change of address for royalty distribution purposes. If you move, or change financial institutions, you must notify **Shawnnay Holland** of these changes. This is your responsibility. Royalty checks and direct deposits sent to old addresses and invalid account numbers are returned to the U.S. Treasury. This will cause a delay in receiving your royalty payment.

If you have new banking information, complete the [SF-3881 ACH Vendor form](#)(link is external) and return to [Shawnnay Holland](#) at the address below:

Shawnnay Holland

E-mail: [shawnnay.holland@nih.gov](mailto:shawnnay.holland@nih.gov)

OFM Royalty Coordinator

NIH Office of Financial Management

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