Technology Transfer & Business Development at OHSU

OREGON HEALTH & SCIENCE UNIVERSITY

OHSU's office of Technology Transfer & Business Development (TTBD) manages and licenses OHSU's intellectual property; links businesses with OHSU technologies and expertise; negotiates agreements that foster partnership and collaboration; and helps to launch new companies based on OHSU research. OHSU has developed a strong infrastructure for commercialization and collaboration. Industry-academic collaborations have continued to grow and diversify, connecting researchers to alternative outlets for crucial project funding. TTBD sits at the forefront of expanding these activities at OHSU.

OHSU research drives discoveries that improve healthcare, create jobs, expand the economy and improve quality of life. One of the primary goals of TTBD is to bridge the gap between promising research and public benefit. To reach this goal we need the participation of everyone at OHSU.

This guide serves as a roadmap for the OHSU community and outlines the services and assistance that TTBD can offer. Whether you need to bring research materials to OHSU or send them to a potential partner, determine whether a discovery you have made should be protected, partner with industry, form a new startup company based on your research, protect unpublished information you have created as part of your job at OHSU, need assistance in generating industry-sponsored research funding, or if you simply have questions on patents and the patenting process - TTBD is the place to start.

Throughout the pages in this guide, you will find resources to inform and guide you in the collaborative process. I hope this guide will answer some of the questions you may have about technology transfer and business development. I encourage you to take advantage of the services TTBD can provide.

TTBD is committed to serving the OHSU community and continuing to build bridges that move discoveries made in the university setting into commercial opportunities. We look forward to answering any questions you may have and working with you in the near future.

Sincerely,

J. Timothy Stout, M.D., Ph.D., M.B.A
Vice President

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Technology Transfer & Business Development at OHSU

The mission of Technology Transfer & Business Development (TTBD) at Oregon Health & Science University (OHSU) is to support the research community by promoting innovation and an entrepreneurial culture that enables the transfer of research from laboratory to market for public benefit.

This guide is intended to provide the OHSU community with an overview of the roles and responsibilities of TTBD as well as the essential elements of technology transfer and business development at OHSU. This guide is organized to answer the most common questions TTBD typically fields from the OHSU community. It contains detailed description of the many processes undertaken by TTBD and makes reference to a number of federal and state statutes and guidelines as well as OHSU policies*.

Why would a member of the OHSU community want to work with TTBD? The reasons are unique to each individual and may include:

- Seeing your work or idea become a product or service that helps the public
- Obtaining unique resources to further your research
- Achieving recognition and financial rewards
- Generating additional lab/departmental funding
- Starting your own business
- Partnering with industry
- Meeting the obligations of a research contract
- Protecting new discoveries made at OHSU
- Protecting the confidential nature of my unpublished research
- Collaborating with outside researchers
- Developing new techology
- Applying and transferring new knowledge to answer important scientific questions

Roles and Responsibilities of TTBD

TTBD is committed to a culture where research and partnerships flourish. TTBD is responsible for assessing the commercial potential of research and other creative ideas, protecting OHSU's **intellectual property** (IP), marketing technologies to **industry**, and negotiating and managing commercialization agreements. TTBD helps to protect and commercialize new **invention**s made at OHSU in order to see these benefit the public.

TTBD helps assure that OHSU meets its obligations as a recipient of various forms of external funding. Some of these activities include compliance and reporting to federal and non-federal sponsors of research, compliance with the **Bayh-Dole Act**, providing reports of **invention**s to sponsors of research, and distributing income received from licensing activities according to institutional and federal guidelines.

TTBD assists the OHSU community in finding and securing **industry**-sponsored funding, acquiring and distributing research resources such as biological materials, compounds, and software, and creating opportunities to bridge the gap between laboratory and commercial opportunities.

TTBD is also responsible for developing external partnerships and for assisting in the launch of new companies based on OHSU research.

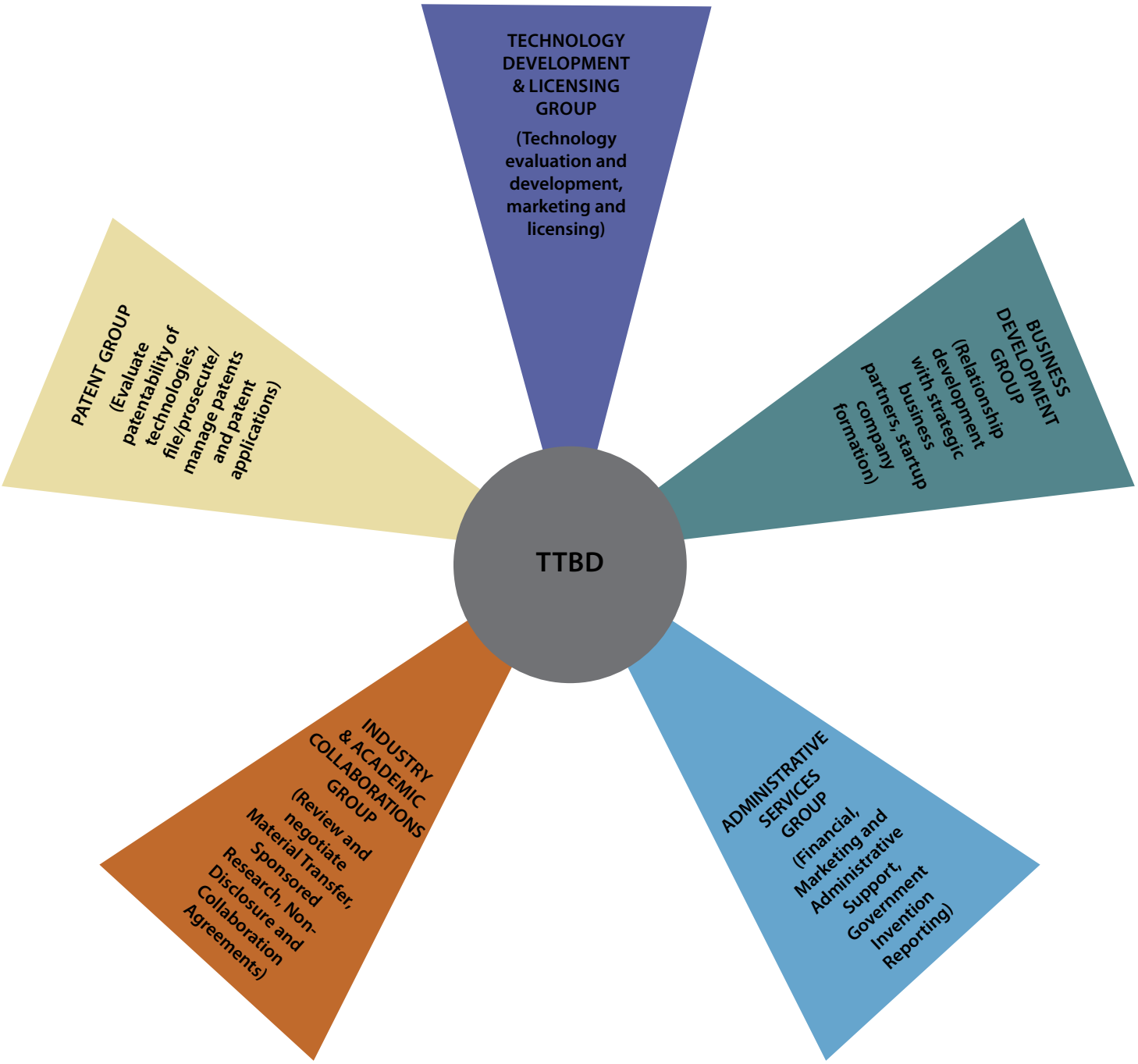
Throughout this guide, the terms invention and technology are used interchangeably.

** While this guide will be updated periodically to include additional information, any published OHSU policy shall supersede material contained in this guide.*

Overview of TTBD

TTBD is an OHSU service unit composed of specialists in licensing, business development, contract negotiation, patenting, business formation and legal matters who have experience and advanced education to best facilitate the transfer of knowledge from the university setting to the public via collaboration with **industry**. This guide is focused on the OHSU community in order to explain how OHSU employees can access and work with TTBD, as well as describe many of the unique functions for which TTBD is responsible. TTBD is organized into several working groups, each of which has distinct roles and responsibilities. The roles of these groups intersect frequently facilitating collaboration amongst the groups. These groups are: i) Technology Development and Licensing Group, ii) Patent Group, iii) Business Development Group, iv) Industry and Academic Collaborations Group, and v) Administrative Services Group. The roles and responsibilities for each of these groups are described further in the remainder of this guide.

Figure 1.1. TTBD Roles & Responsibilities



TECHNOLOGY DEVELOPMENT & LICENSING

Over fiscal years 2010-2012, TTBD received an average of 120 new IP Disclosure Forms per year.

US legislation dealing with intellectual property arising from US federal government-funded research, the Bayh-Dole Act of 1980, gave US universities, non-profits, and small businesses control over their own inventions including the ability to commercialize and license out university intellectual property. In addition to carrying out the mission of the Bayh-Dole Act , the Technology Development and Licensing Group seeks to commercialize university inventions, whether federally funded or not, by i) evaluating new **invention**s submitted by OHSU employees, ii) assessing commercial and IP potential, iii) identifying **technologies** appropriate for licensing, iv) working with the Patent Group to protect the IP, v) finding **licensees**, vi) transferring the **technology** into the public domain by way of **license agreement**s, vii) and drafting, negotiating and monitoring **license agreements**.

IP DISCLOSURE

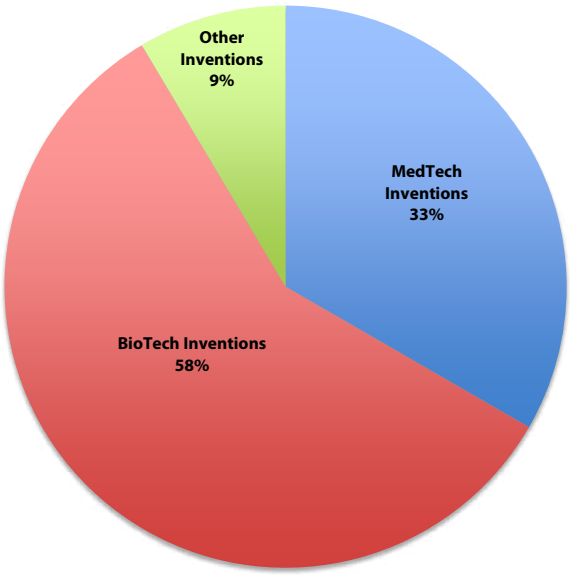
This process usually starts with the initial **invention** disclosure. The initial invention disclosure is sometimes the first written description of a new invention and is the formal way of documenting a new invention with OHSU. The first step for investigators in the **invention** disclosure process is completion and submission of the **IP Disclosure Form**. If there is uncertainty as to whether an **IP Disclosure Form** is warranted or not, please contact us.

Patents, one form of IP protection and the most common protection sought by TTBD, focus on what the **invention** is and what the **invention** does as a process (method) or some combination thereof. When submitting the **IP Disclosure Form**, it is helpful to think about what the final product or service might look like, and answer the following with two to three simple sentences per question: i) describe the product/service, ii) describe the technical problem the product/service is intended to solve, iii) describe how the product/service solves the technical problem better than existing technology by providing details on currently available products/services, iv) list the key features of what the product/service looks like and the features that differentiate it from known products, and v) describe the progress to date.

It is the physical description and design detail of the product/service rather than the function of the product that make up the key features. In some instances the key description takes the form of detailed engineering specifications. Detailed information on available products/services and how the disclosed product/service differs allows TTBD to make a better evaluation of the patentability of the product or service. The more developed or mature a product and/or service, the easier the questions can be answered.

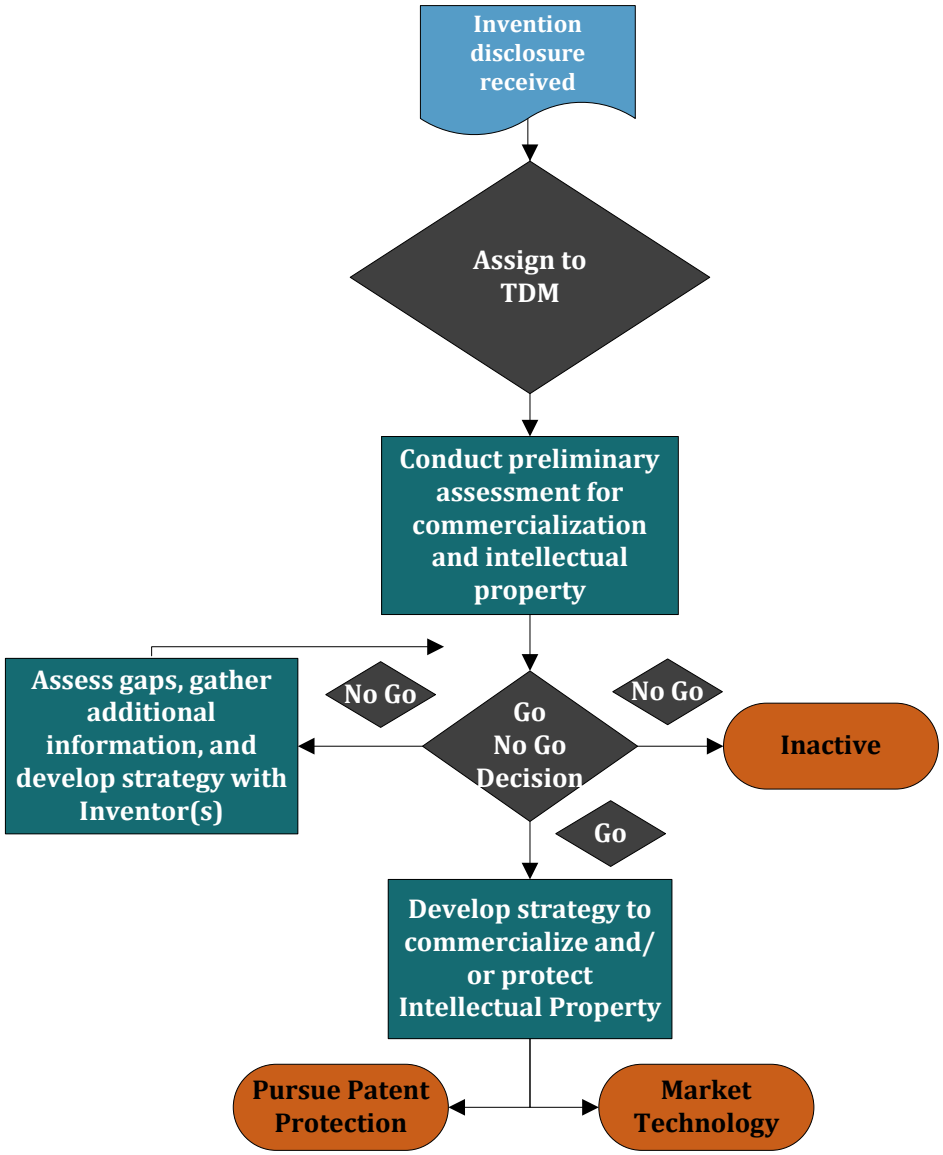
TTBD reports metrics to the Association for University Technology Managers (AUTM), which publishes the results in an annual survey available to the public.

Figure 2.1. Inventions in Fiscal Year 2012



IP DISCLOSURE REVIEW

Figure 2.2. Invention Disclosure Process



After the submission of the **IP Disclosure Form**, the **invention** is assigned to a Technology Development Manager (TDM) in the Technology Development and Licensing Group who performs a preliminary assessment for commercialization and protection. One component of the commercialization assessment is a market analysis of the potential product and competitive landscape to determine the likelihood a **licensee** would be willing to license the **technology**. The IP assessment determines the type, if any, of IP contained in the **technology** and a preliminary IP landscape search (as appropriate if commercial potential is identified). A more detailed **patent prior art** search, in conjunction with the Patent Group, may also be completed. At this point, the assigned TDM meets with the **inventor**s to discuss this preliminary assessment, observe the prototype or laboratory results, and review the next steps in the evaluation process. A "Go, No Go" decision point is discussed with the following outcomes:

NO GO DECISION

It may be determined that no further action is justified by TTBD because the **technology** may not be protectable or may have significant market viability concerns (such as small market size, limited **industry** interest, or too many competing products). At this point the **technology** is inactivated and no longer pursued by TTBD. Alternatively, after the preliminary assessment, the TDM may require additional information from the **inventor**(s) to further assess the information sent with the **IP Disclosure Form**, to determine if gaps exist, to strategize on ways to develop additional data to strengthen the position, and to determine a strategy to move forward. A more detailed **prior art** search by the Patent Group may also be needed.

Following a No Go decision and the decision by TTBD to no longer pursue the **technology**, there are several options if the **inventors** would like to pursue commercial development on their own. If the **invention** utilized any funding from the government* in its creation, TTBD must either decline election of title to the **invention** and relinquish all rights in the **invention** to the government, or the technology can be licensed directly to the inventors. Once rights are returned to the government, the inventors can petition the government for title to the **invention** through a formalized process. TTBD can assist the **inventors** with this process. There are no guarantees that the government will grant the inventor's petition, and during the timeframe that the government is making its decision, the **inventors** must take full responsibility for all patenting actions and expenses, if any. If the **invention** did not utilize funding from the government, the **technology** can be licensed directly to the **inventors** or the **inventors** may request that OHSU waive all or part of its rights to ownership of the **invention** per **OHSU Intellectual Property and Royalty Distribution Policy**.

**Throughout this guide, the word government is used to signify that of the United States of America.*

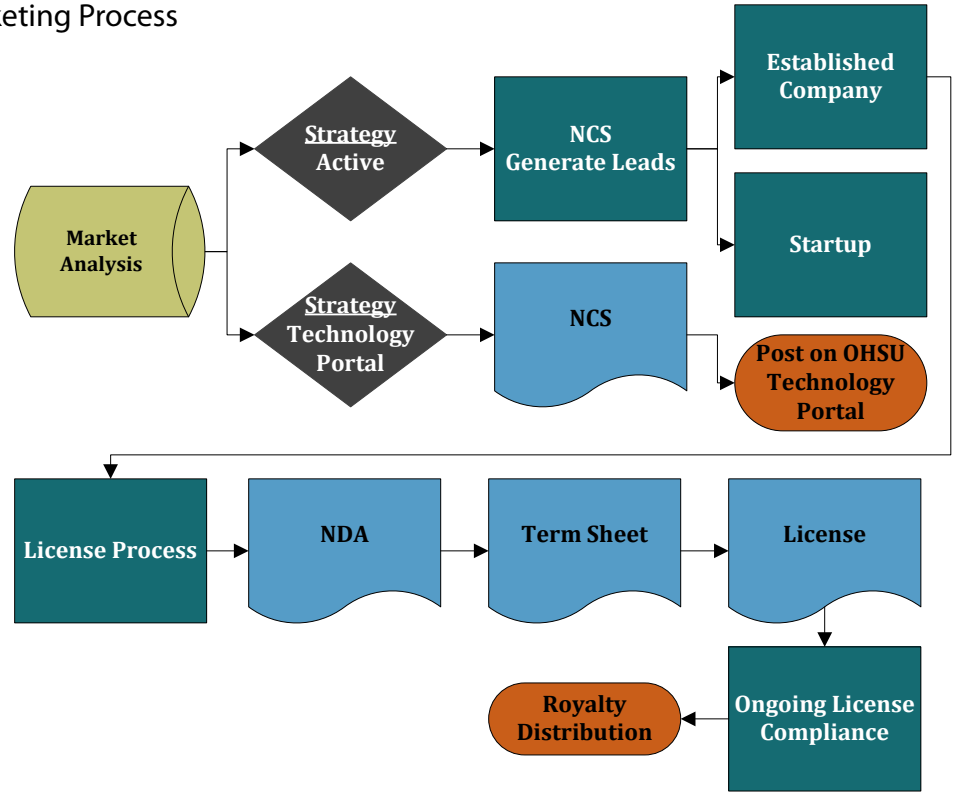
GO DECISION

Once the TDM believes there is a strong position for commercial potential and IP has been identified, then an initial "Go" decision is made. At this point a more developed strategy to protect the IP and market the **technology** is developed, with the goal of licensing the **technology** to an existing **industry** partner or pursuing the formation of a **startup** company. **Patents** are key to **technology** transfer and commercialization of OHSU technologies. They often provide the most valuable protection for OHSU **inventions** and the best chance for licensing opportunities. Prior to and during the IP Disclosure Review, TTBD highly urges **inventor**s not to publish or discuss any unpublished information on the **invention** with any person outside OHSU before talking to a TDM in TTBD. Non-OHSU individuals and outside **industry** representatives may be on campus but are not covered under the general OHSU confidentiality regulations. In order for these outside individuals to receive any unpublished information, they must first have signed a **Non-Disclosure Agreement** (NDA), which TTBD can put in place with this outside party. Only authorized representatives of OHSU can legally sign and bind OHSU into an agreement such as a NDA. **Inventors** are strongly encouraged to contact TTBD.

IP MARKETING

Once a **technology** is given a "Go" decision, a marketing strategy is developed which can take two forms, the first of which is a web portal developed by TTBD. For all technologies requiring marketing, a **non-confidential summary** (NCS) is created by the TDM. The NCS is typically posted on the TTBD Technology Portal website for marketing and licensing. On the TTBD Technology Portal each **technology** posted has certain non-**confidential information** that the public can view. If a potential partner is interested in learning more about a specific **technology**, or set of technologies, the appropriate TDM and corresponding contact information is listed.

Figure 2.3. IP Marketing Process



Tangible materials produced by OHSU that may or may not be patentable are made available to a licensee who wishes to use them under a **license agreement**. In general, materials are provided to other academic research institutions free of charge using a **Material Transfer Agreement (MTA)** or a permissive **license agreement**. **Industry** may be charged a license fee for the use of the materials or software and therefore a proprietary **license agreement** is used to set the terms and conditions of use. Patent protection is not automatically necessary for licensing **tangible materials**. Most **tangible materials** are posted on the TTBD Technology Portal. The TTBD Technology Portal has shopping cart functionality that allows individuals to select which materials are of interest to them, place the materials in a shopping cart, identify the license fee for each material, and decide whether or not to license such materials by way of a click-through **license agreement**.

The second marketing strategy is for those technologies requiring active marketing [those technologies requiring an exclusive **licensee**, high-value technologies, or those technologies with **intangible assets** such as **patents** and high value **copyrights**]. For these technologies, the TDM generates leads and directly contacts companies who may be possible **licensees**. When a potential **licensee** wants to learn more about a **technology** and possibly obtain confidential and unpublished information, the TDM puts a NDA in place.

TDMs have many sources and strategies to market **invention**s and identify potential **licensees**. Often existing relationships the **inventors**, the TTBD staff, and other researchers have with **industry** are critical to marketing a **technology**. Market research and related **patents** can also assist in identifying prospective **licensees**. TDMs examine other complementary **technologies** and agreements to assist in these marketing efforts. TDMs leverage conferences and **industry** events and make direct contacts with companies. Faculty publications and presentations are often excellent marketing tools as well. It can take months and sometimes years to locate a potential **licensee**, depending on the attractiveness of the **technology**, its stage of development, competing technologies, and the size and dynamics of the market. The **inventor**s' active involvement can dramatically improve the chances of matching an **invention** with a potential **licensee**. The most successful licensing results are obtained when the **inventors** and the TDM work together as a team to market and license the **technology**.

IP LICENSING

Once a prospective **licensee** expresses an interest in taking a license to a **technology**, the type of license (non-exclusive or exclusive) is determined and a **term sheet** is exchanged. This process is interactive, commonly taking several iterations before both TTBD and the **licensee** come to a mutual understanding on the financial and commercial development terms. The **licensee** may also want to first enter into an **option agreement** while evaluating the **technology**, negotiating terms in the **term sheet**, or gathering more information to firmly make a decision as to whether or not to pursue a **license agreement**.

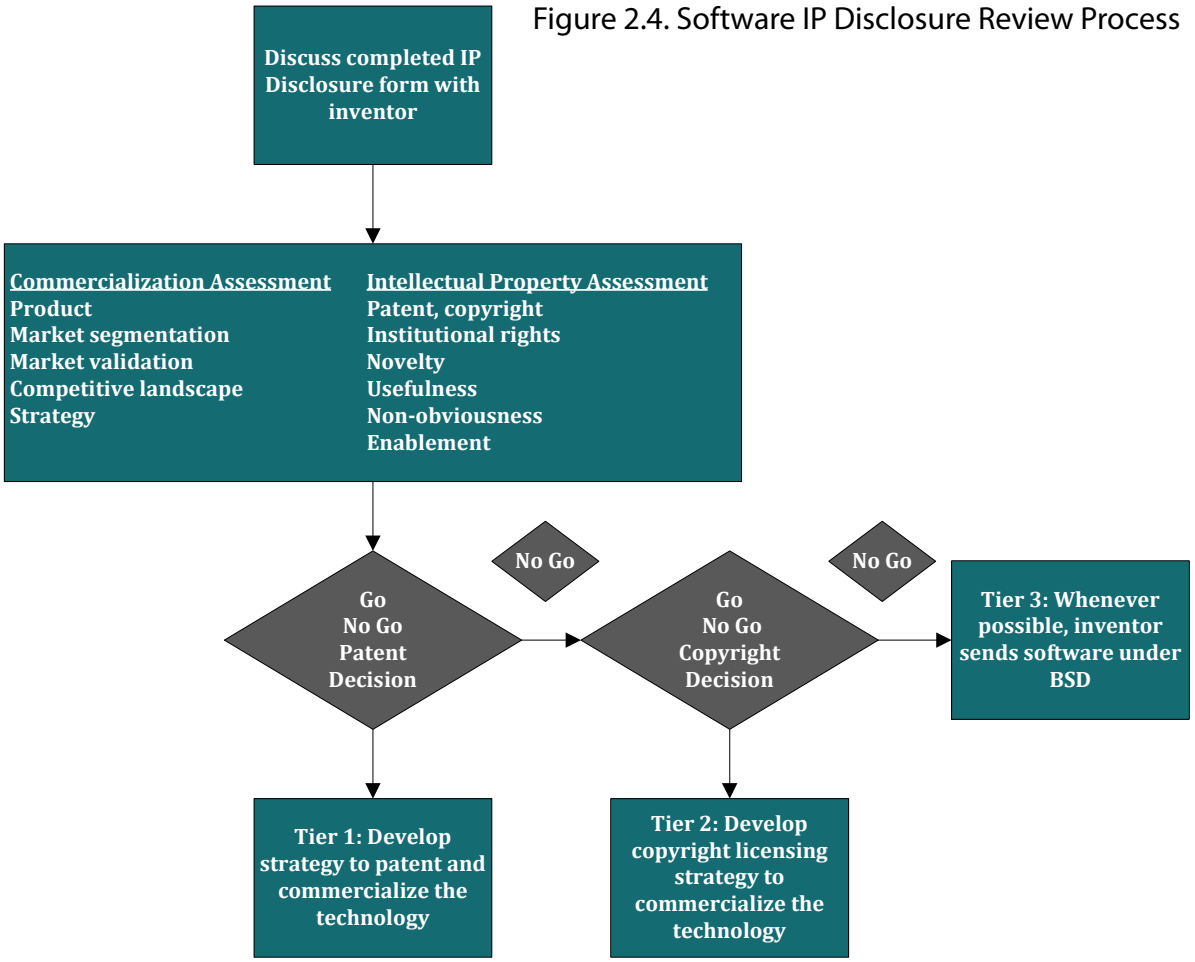
Negotiation of the **license agreement** may take several drafts and multiple discussions with the **licensee** before the business and legal language are agreed upon. **License agreements** include terms that require the **licensee** to meet certain performance requirements and to make financial payments to OHSU. Following execution of the **license agreement**, **royalty income** based on milestones and/or royalties from sales of products or services may be received by TTBD. **Inventor**s share in this royalty as outlined in the OHSU **Intellectual Property and Royalty Distribution Policy** as defined on page 41 of this guide (https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/).

The TDM manages the **licensee's** compliance with the terms of the **license agreement** after it has been executed. The **licensee** continues the advancement of the **technology** and makes other business investments to develop the product and/or service. These steps may entail further development, seeking regulatory approval, sales and marketing support, training, and other activities. Commercial development reports and **royalty income** payments are tracked by TTBD. This requires an ongoing relationship with the **licensee** in conjunction with the TDM, Patent Group, Administrative Services Group, and OHSU Central Financial Services.

LICENSING SOFTWARE

Software code is automatically copyrighted upon creation with minimal registration requirements. To be eligible for a patent, the software architecture must be shown to be novel, useful, non-obvious, and enabled as described in detail below. If the software does not meet the requirements for patent, then the license is limited to the copyright. Copyright only protects the expression of the invention (i.e. the code as written), and therefore cannot be used to prevent reverse engineering. Patent protects the invention (i.e. the architecture/functionality) which can be expressed in multiple forms, thereby providing much broader protection. Licensing of software can be for the copyright, patent, or both as described further below.

Figure 2.4. Software IP Disclosure Review Process



The rights in **copyright** can be licensed a variety of ways, including via permissive licenses, copyleft licenses, and proprietary licenses. Permissive and copyleft licenses are commonly referred to as open source licensing, of which there are many flavors that offer key distinctions on what can and cannot be done under those licenses. Permissive licenses have the fewest restrictions on users and adopters and often only require that the original creators be attributed in any distribution of the work or derivative work created and distributed. Permissively licensed software may be incorporated into "closed" proprietary programs with no requirement that the source code be disclosed if the combined software is distributed.

Examples of permissive licenses include the Berkeley Software Distribution (BSD) and MIT licenses. Copyleft licenses require derivative works to be open source and distributed under the same licensing terms as the original distribution license. Examples of copyleft licenses include the General Public License (GPL) and the Lesser GPL. The GPL has strong reciprocity requirements that guarantee perpetual open source access to the work, even if it is incorporated into another entity's software as a derivative work. The Lesser GP has some weaker copyleft requirements and allows for linking to proprietary code under certain circumstances. Proprietary licenses have the most restrictions and limit uses considerably.

Generally, proprietary licenses are for software that can be commercialized for money. Key questions around whether to share software include: i) will sharing the software establish the lab as a leader in the field, ii) are users likely to submit their own software improvements, iii) will the software gain value with more use and/or validation by shared use, and iv) will user feedback play a crucial role in later improvements?

Key questions around whether not to share software include: i) will user support be difficult/time-consuming due to complicated software and/or lack of documentation, and ii) does the software give the research group a competitive advantage on grants and collaborations?

Programmers intending to commercialize their software must be aware of any code that was obtained under an open source license and understand the implications of that process.

IP ABANDONMENT

TTBD cannot pursue every **invention** that is disclosed. **Patents** are by far the most expensive form of IP to protect. Therefore, the decision to seek or continue **patent** protection on a particular **technology** is closely examined. There are times when TTBD sees commercial potential in an **invention** when first disclosed and decides to file for **patent** protection. However, if TTBD is unable to find a **licensee**, TTBD may decide to no longer pursue **patent** protection. This may occur at any point during the **patent** prosecution process and is influenced by the evolving commercialization landscape. When TTBD determines that no further efforts on licensing the technology should be expended, the technology can either be inactivated and all patent rights abandoned, the rights in the technology can be transferred to the government (if the technology originally was created from the use of government funding), the rights in the technology can be licensed directly from OHSU to the inventors, or if the technology was not created from the use of government funding then the inventors may request that OHSU waive all or part of its rights to ownership of the **invention** per **OHSU Intellectual Property and Royalty Distribution Policy.**

Over fiscal years 2010-2012...

>80% of the license/ option agreements executed per year were licensed/ optioned to small companies (those having 500 or fewer employees).

17% of the license/ option agreements executed per year were licensed/ optioned to large entity industry partners (those with more than 500 employees

TTBD entered into an average of 51 new license/option agreements each year. Of these, an average of 10 new license and option agreements were exclusive each year.

LICENSING AND IP PROTECTION STRATEGIES

A licensing and patenting strategy is not only different from a grant and publication strategy, the two strategies are often at cross-purposes with one another. Different rules are followed, different goals exist, and there are different competitors. While there is no guarantee that diligently following rules to obtain **patent claims** will result in an issued **patent** or a valuable **technology**, there are ways to increase the chances that an **invention** can be protected and licensed.

Identify projects that could lead to patentable **inventions** and treat those projects differently. An important scientific discovery may not result in a valuable **invention**. By the same token, valuable **inventions** are often the result of projects that are not the main focus of the laboratory. TDMs are trained to help identify those projects that are most appropriate to develop using a patenting and licensing strategy. In general, such projects have as an end result a product or service that can be sold. A discovery involving a mechanism of action, identifying the best of a number of known courses of treatment, or explaining a biological process is less likely to be appropriate for patenting and licensing.

Delay publication until the product takes shape. Many technologies from academic research laboratories are **publicly disclosed** before a lead product or proof of concept has been developed. This results in difficulty in obtaining commercially viable **patent claims** and an increased risk for potential **licensees** to take on further development. Consequently, **technologies** that are publicly disclosed before a lead product or proof of concept has been developed are difficult, if not impossible, to license and commercialize even if a **patent** application was filed prior to the **public disclosure**. Below are some examples of the level of development necessary before filing for **patent** protection on a particular **invention**.

TTBD manages over 350 active licensing/ option agreements.

DIAGNOSTIC TESTS AND DIAGNOSTIC/THERAPEUTIC-TYPE PROCESSES

While statistical significance is the minimum required for patentability in diagnostic tests, the key question to keep in mind with a diagnostic **invention** is, "Would a doctor be able to make a recommendation to a patient on the basis of results of this test?" It is useful to understand the false positive and especially the false negative rate. Develop a reagent or reagent formulation (such as a new primer/probe set or antibody) that ties the test to a particular composition of matter or apparatus (i.e., a device). Try to develop newly optimized PCR or antibody reagents rather than those provided by companies – the actual sequences and formulations are often kept proprietary.

THERAPEUTIC COMPOUNDS

The optimal plan is to wait on filing a **patent** application or publishing the invention until a lead compound has been shown to work in an established in vivo model. For small molecules, often the key is to focus on quality and not quantity – focusing on those compounds that have been made and tested and shown to work rather than those that could be made. For antibodies, **inventors** should make sure to provide antibody sequences and focus on complementary determining regions (CDRs).

METHOD OF TREATMENT

Claims in **patent** applications to methods of treating diseases using known drugs (drugs not invented at OHSU) are becoming more and more difficult to obtain. At a minimum, what is needed is a result in an established animal model of disease (in vitro assays are not enough). Additionally, these claims are difficult to enforce and license.

DRUG TARGET

Claims in a **patent** application to a molecule as a target for treatment of a disease have never been allowed. By and large, such **patent claims** evolve into a method of screening compounds for drug characteristics. These are also difficult to license in that a potential **infringer** can perform the screen without anyone's knowledge.

BIOLOGICAL SEQUENCES

Biological sequences are potentially patentable as compositions of matter if they do not occur in nature. A cDNA derived from a spliced mRNA; an amplified PCR fragment; a purified nucleic acid or protein; or an artificial, recombinant, or chimeric biological sequence are all potentially patentable under current law. However, these sequences must also meet the requirements of novelty, utility, non-obviousness, and enablement described in detail below. Any naturally

occurring protein or nucleic acid sequence in the context of its native cell or organism is not and has never been patentable subject matter.

SOFTWARE

Automating a process in and of itself, as well as manipulation or reorganization of data does not make a process patentable. Further, a software program itself is not an **invention** per se. Software is the medium of implementing the **invention**. The key is to have a practical application of the mathematical algorithm vs. the abstract idea itself. It should not be purely abstract mental steps, even if performed by a computer. How the computer software/hardware/database is specifically programmed to do the practical application needs to be specified. The line of patentability with software lies somewhere between logical steps that humans can perform without the aid of a computer versus those that require a computer to carry out.

DEVICES

If the key feature of the device resides in the software, then the software notes above apply. If the software interacts with the hardware (and requires hardware in a specific format/combination) then that is key to identify, detail and describe sufficiently, and think about possible workarounds. If the key innovation features are solely hardware, it is extremely important to detail all of the components/features of the device and how they all interact with one another to solve the problem. All possible ways of making the device and its components should be thought out and described. Testing the device against the gold-standard device/solution in that market space is preferable. If the device is solving one specific problem that the currently available solutions do not do at all (or do not do well), then having data that shows it specifically solving that problem better compared to the other available solutions is important.

A **patent** protected **invention** can be valuable and more easily licensed if the **patent** coverage obtained can cover detectable violators of the **invention**. In the preparation of the **patent** application and during its prosecution, it is good practice to analyze the potential for work-arounds and focus the **patent** claims to cover the **invention** in the best way possible for downstream enforcement. **Patent** claims that describe the **invention** rights in a way that would encompass actual products that are sold utilizing the **invention**, and thereby cover the distributors and/or manufacturers of such products, are highly desirable in the licensing marketplace. In contrast, **patent** claims that describe the **invention** rights in ways that only cover methods of use, or can be easily worked around, are harder to enforce (e.g., harder to detect **infringers**) and therefore are less desirable by companies for in-licensing.

PUBLICATIONS

Inventors should avoid disclosing an **invention** for the first time in a meeting poster presentation. Often, the abstracts are made public prior to such a meeting, resulting in a rushed decision on filing a **patent** application and a too-early disclosure. If a manuscript has already been submitted to a journal, care should be taken with online pre-publication of the manuscript (as that online pre-publication counts as a publication for **patent** purposes and can severely limit **patent** rights). When submitting a manuscript in which an **invention** is disclosed, make sure that the **invention** is the main focus of the manuscript. Disclosing an **invention** for the first time as an aside in a manuscript is similar to disclosing the **invention** for the first time in a poster presentation and can jeopardize protection.

Most preferably, a first **patent** application is filed after a proof of concept has been proven/made and/or once a commercial lead product has been selected, but well in advance of its first **public disclosure**. **Patent** filing, discussed in further detail below, can easily dovetail with publication. In many cases, if the **patent** professional filing the application is presented an early draft of a manuscript that includes a materials and methods section, a results section, figures, and figure legends, the **patent** professional can have sufficient time to write up most of the **patent** application, discuss with the **inventors** additional details that need to be provided in the **patent** application, and file a detailed application well before the manuscript is published.

As mentioned above, there are considerable differences between patenting and licensing strategies and an academic-style grant and publication strategies. Another difference to consider is forward-looking statements in presentations and manuscripts. A forward-looking comment in an academic poster or discussion section of an academic paper may be used in an obviousness rejection in a **patent** application being sought by TTBD. These forward-looking statements often result from suggestions in the academic poster or paper of the next experiments to be performed. If the experiments are described or suggested and the results are exactly as predicted, then any **invention**s enabled by those suggested experiments would likely be unpatentable over the comment in the prior discussion in the paper or poster. Thus, providing forward-looking statements can have a negative impact on the ability to license an **invention**.

TECHNOLOGY DEVELOPMENT & LICENSING FAQs

What happens after the submission of an IP Disclosure Form?

The **IP Disclosure Form** is immediately assigned to a TDM for evaluation. The TDM conducts a preliminary commercialization and IP assessment and then meets with the **inventor**s to discuss the preliminary analysis and the next steps.

How long does the licensing process take?

The process from reviewing a new **invention** in an **IP Disclosure Form** to protecting the **technology** and finding the right licensing partner may take months – or even years – to complete. The amount of time depends on several factors, including the development stage of the **technology**, the market for the **technology**, competing technologies, the amount of work needed to bring a new concept to market-ready status, and the resources and willingness of the **licensee**(s) and the **inventors**.

When is a discovery an invention?

TTBD encourages the submission of **IP Disclosure Forms** for all discoveries, creations and developments that may solve a significant problem and/or have significant value. When in doubt, contact TTBD to discuss the possible **invention** with a TDM.

When should an IP Disclosure Form be completed?

An **IP Disclosure Form** should be submitted prior to any form of publication or other **public disclosure** that describes something new that has been developed which could be used as a product or service. Once **publicly disclosed**, an **invention** may have restricted or less potential value for **patent** protection and can be more difficult to license. Be sure to inform TTBD and the appropriate TDM of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal, dissertation/masters thesis, publication, or other public presentation that may include any aspect of the **invention**.

Should tangible materials be disclosed?

Yes, if new **tangible materials** would benefit other researchers then they should be disclosed. **Tangible materials** are often very valuable. If there are **tangible materials** that may be valuable, TTBD works to develop an appropriate protection, licensing, and distribution strategy. Please use an **IP Disclosure Form** to disclose **tangible materials** to TTBD.

Can OHSU accept equity (stock) in license agreements?

Yes, OHSU can accept equity as part of the financial terms of a license. This happens most commonly in **license agreements** for small **startup** companies. Equity may be substituted for other cash considerations that are often difficult for **startups**. It is also a way for OHSU to share some of the risk associated with the **startup**. A decision to take equity must make sense for both OHSU and the company.

What is the purpose of listing the sources of funding for an invention?

If funds from the government were used in the creation of the **invention**, then it is a requirement to submit a prompt **IP Disclosure Form** to TTBD. This enables TTBD to report the **invention** to the appropriate government-funding agency. Similar reporting requirements may exist for other sponsors of the **invention** as well.

Who owns inventions that OHSU employees create?

Ownership of inventions that OHSU employees create is covered under the OHSU **Intellectual Property and Royalty Distribution Policy** (https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/)**.**

What happens if IP is co-developed with investigators at another university?

An **Inter-Institutional Agreement** (IIA) is needed. IIAs describe the terms under which two or more institutions (generally two universities) collaborate to assess, protect, market, license, and share in any costs incurred in protecting IP (i.e., **patent** costs) and revenues received from licensing jointly owned IP.

What happens with copyrighted work that is owned entirely by OHSU and does not have commercial potential? Can another university use it for a "not-for-profit" purpose?

Yes. The Berkeley Software Distribution license is commonly used for this purpose and TTBD can help with the process.

Is it permitted to post a software program developed at OHSU on the internet to allow other users to download it and use it for not-for-profit purposes?

Yes. The Berkeley Software Distribution license is commonly used for this purpose and TTBD can help with the process.

Why is it necessary to use the Berkeley Software Distribution license when a product or technology is free for others to use?

There are issues other than money to consider. The Berkeley Software Distribution license disclaims warranty and provides the recipient a "clean" title to use the software and make modifications to the software.

PATENT

The OHSU Patent Group has a primary goal of making OHSU's patent portfolio transparent to all stakeholders including inventors, OHSU administration, Technology Development Managers and others within TTBD, licensees, the general public, other institutions, outside patent counsel, and even potential infringers. We strive to make our patents clear by seeking only the patent claims we are legally entitled to. Clear patents make our technologies easier to license, discourage infringement and work arounds, and result in a patent portfolio that is easier to manage.

The Patent Group works with the Technology Development and Licensing Group to review those **invention** disclosures having commercial promise to determine if there is protectable IP. The Patent Group focuses its efforts on filing and securing **patent**s for OHSU technologies having commercial promise. The Patent Group works closely with the TDMs to determine the scope of patentable **claims** on such technologies and to file, prosecute, and maintain OHSU **patent** applications.

The United States **patent** system is based on Article I, Section 8, Clause 8 of the U.S. Constitution, and the first United States Patent Act was passed in 1790. The purpose of the **patent** system is to promote innovation by granting exclusive rights to **inventor**s in exchange for a detailed description of how to make and use the **invention** that is made available to the public.

Laws of nature, physical phenomena, and abstract ideas themselves are not patentable subject matter. The application of laws of nature, physical phenomena, and abstract ideas to solve problems are patentable subject matter. For an **invention** to be eligible for **patent** protection, it must be **new, useful, and not an obvious derivation of something that has already been invented.** Further, to receive **patent** protection on the **invention**, the **inventor** must provide sufficient detail to describe how to make and use the **invention**. These requirements are discussed in detail below.

PATENT REQUIREMENTS

A **patent claim** may not be granted by a **patent** office unless it meets all of the following requirements:

NOVELTY

The **claim** must describe a novel **invention**, that is, that no other person created the **invention** previously. In practice, this means that the **invention** is not described in any **prior art** reference.

While most novelty rejections can be overcome by clarifying differences from the **prior art** or amending **claims**, this is not the case when the novelty rejection is due to the **inventor's** own disclosure of the **invention** in a publicly available reference prior to the filing of a **patent** application. While the United States allows a one-year grace period between **public disclosure** of the **invention** and the filing of a **patent** application, this is not the case in most other countries. Further, with changes to United States **patent** law starting March 16, 2013, the one-year grace period can be less powerful if someone else independently invents the same thing and files first. Europe in particular allows no grace period – **public disclosure** of the **invention** at any time results in a dedication of the **invention** to the public domain and loss of ability to obtain issued **patents**.

UTILITY

The **claim** must describe a useful **invention**. It may also be said that the **invention** must have industrial applicability. Basically, this means that the **invention** must provide some degree of solution to a problem.

NON-OBVIOUSNESS

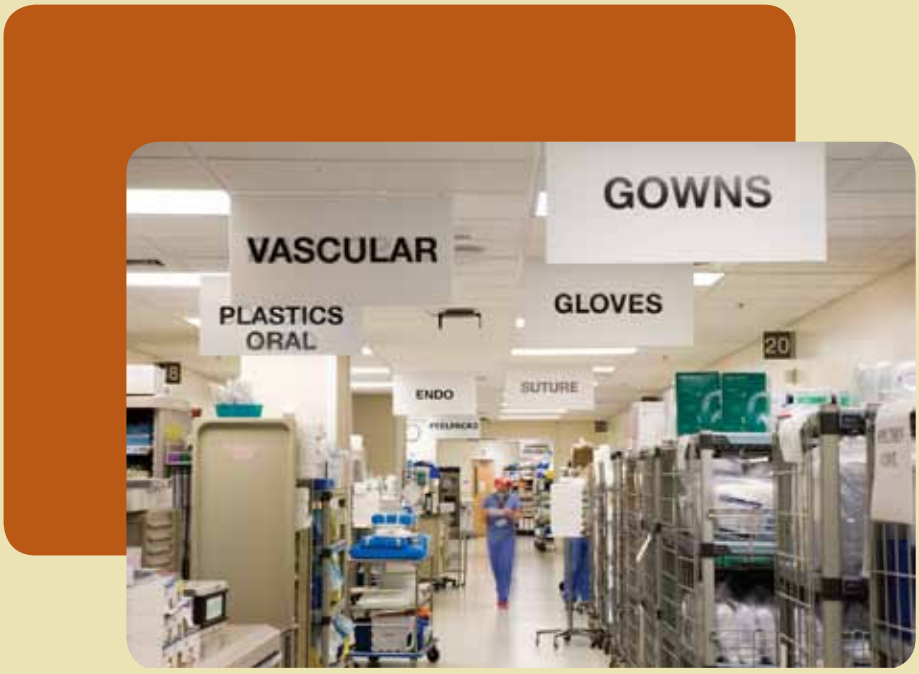
The **claim** must describe an **invention** that is not an obvious derivative of what is already disclosed in **prior art** references. Unlike a novelty rejection, in which a single **prior art** reference describes the **invention**, an obviousness rejection allows the combination of two or more **prior art** references with a suggestion that a person having ordinary skill in the art to which the **invention** pertains would have been able to combine the two or more references to make and use the claimed **invention**. Obviousness is a difficult concept to understand. In addition, it is very common during the process of **patent** prosecution that an obviousness rejection of many if not all of the **claims** will occur. It is always best to have clearly noted in the **patent** application examples of any technical hurdles overcome and unexpected results obtained so that those can be clearly referenced to overcome an obviousness rejection.

One over-simplistic example of obviousness is the following: look at an object on someone's desk and imagine that it is a new **invention**. Now imagine that it is another color. For example, if the object is a black binder clip, imagine that it is painted blue. If no one had ever described a blue binder clip, then the blue binder clip would be novel, but it would be an obvious derivative of the black binder clip. In other words, if someone in the paper fastening arts wanted to produce a blue binder clip and he or she could have found a **prior art** reference disclosing the black binder clip and also a reference for making metal items blue, then a **patent** application on the blue binder clip would be rejected on the basis of obviousness.

Like novelty rejections, obviousness rejections can be overcome by clarifying differences in the (combined) **prior art**, if there are any. If there are no clear differences, then an obviousness rejection can be much more difficult to overcome. More often than not, the applicant must provide evidence of a **secondary factor of non-obviousness**. Evidence of **secondary factors of non-obviousness** is preferably provided in the **patent** application itself or in the form of a declaration by the **inventor** or, preferably, someone unconnected to the **invention** that states the evidence for the secondary factor. Declarations take a great deal of time and effort on the part of internal and external **patent** professionals, the **inventors**, and the outside consultants (when a party unconnected to the **patent** is making the declaration), and therefore incur significant extra expenses. In addition, the person signing the declaration must certify that everything in the declaration is true to the best of their knowledge – otherwise the person signing the declaration could be committing perjury. Declaration practice should only be used in those **inventions** that are highly likely to result in commercial products (generally, licensed **technologies**). **Patents** that issue because of declaration arguments are often challenged if they are litigated. As a result, it is best to avoid declarations.

ENABLEMENT

The **invention** described by the **claims** in the **patent** application must be sufficiently described by the specification/description of the **invention** in the **patent** application such that "someone skilled in the art" has enough information to make and use the claimed **invention** without undue experimentation. Technically, this means that a "someone skilled in the art" should be able to recreate the **invention** from what is disclosed in the specification. While the **claims** describe the **invention** formally, the specification is what provides the support to the **claims**. Terms used in the **claims** should be explicitly defined in the specification, especially if the scope of those terms goes beyond their common usage in the field. The specification also should provide evidence that the **inventor** is in possession of the **invention** at the time of filing the **patent** application. In the engineering fields, the specification includes technical drawings and detailed descriptions of the components in the drawings.



In the biotechnology arts, the specification includes sequences of biomolecules and/or chemical structures as appropriate, data obtained from testing the **invention** including figures and figure legends, and the materials and methods describing how the data were obtained. Enablement rejections are usually overcome by amending or narrowing **claims** as appropriate and often result from an incomplete disclosure of the **invention**, filing for overbroad **claims**, and/or filing the **patent** application too early in the process of making the **invention**.

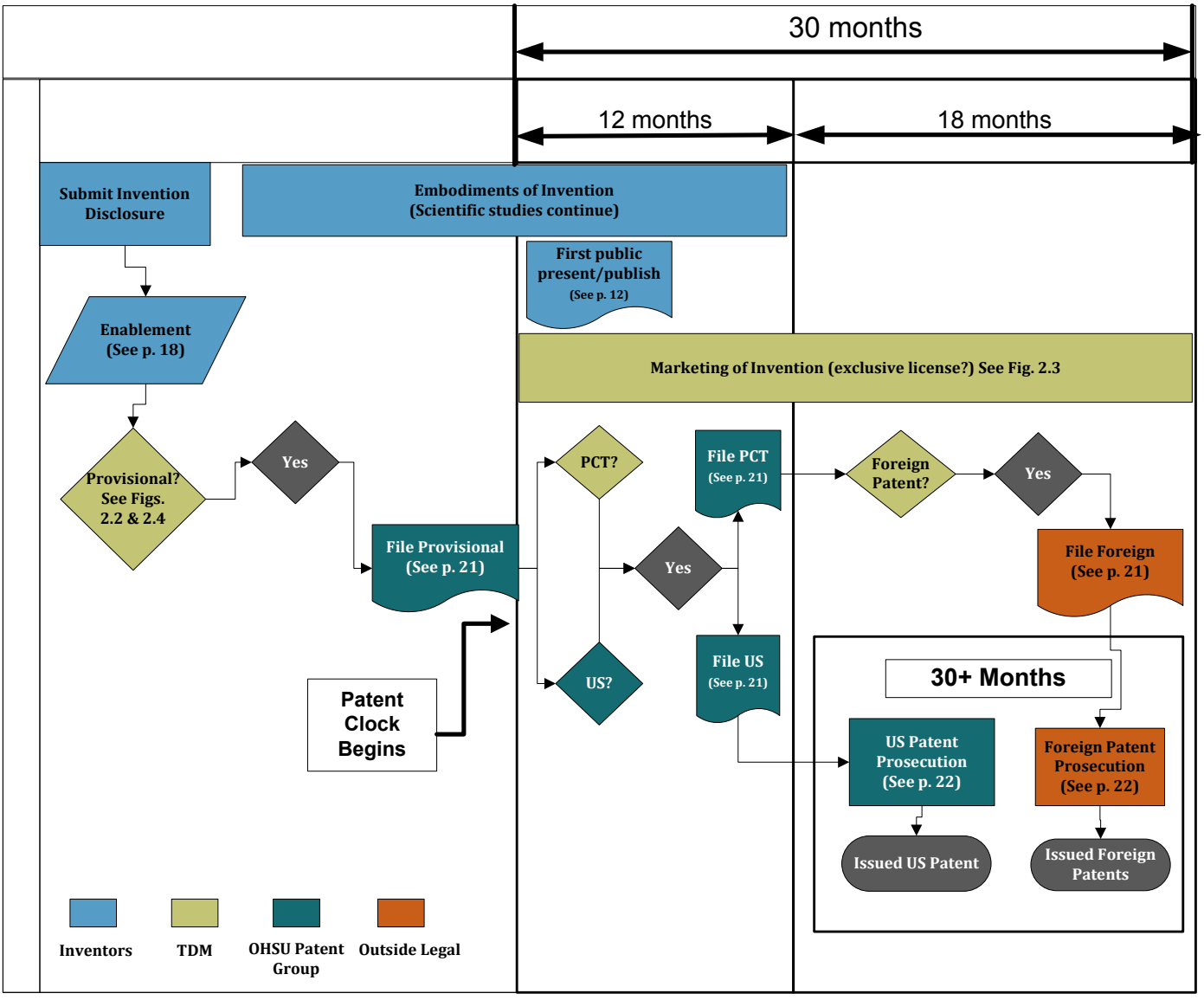
At its base, a **patent** application discusses the **invention** as the solution to a problem. In the biotechnology/pharmaceutical space, the **patent** application generally focuses on a description of what the **invention** is and that it works as opposed to the mechanism of action (how it works). The mechanism of action is included in a biotechnology/pharmaceutical **patent** application, but it is generally not the main focus of the application. In the engineering/device and software arts, the specification includes technical drawings, design documents depicted as flowcharts, and detailed descriptions of the components and steps shown in the drawings and flowcharts, thereby conveying functionality and operability. Specifically in the software arts, while it is important to describe how the software is used from the perspective of the end user to give it context, the essential description is an explanation of how the software operates from the perspective of the computer. Flowcharts in a patent appication convey what is happening at a technical level via visualizations of the logic of how the software operates at a broad level and at in-depth step by step routines and subroutines.

PATENT PROCESS

Obtaining issued **claims** from a **patent** application is a slow process. From the filing of the initial application to the grant of **claims** may take three to seven years or more. The term of a **patent** is 20 years from the initial non-provisional filing date, but **claims** are only enforceable after the **patent** has issued or been granted. Furthermore, to receive worldwide **patent** coverage, a **patent** application must be filed in every country in the world. In addition, many **patents** can result from the same initial **patent** application. This is because the initial application may describe a number of **inventions** or different aspects of the **invention** and each aspect may be important for licensing and enforcement of the **patent**. This means that each separate **invention** or aspect of the single **invention** within follow-on applications will be seeking a different or even very slightly different set of **claims**.

At OHSU, the **patent** process is tightly bound to the licensing process described above. Without sufficient royalty revenues or a licensing deal that requires the **licensee** to cover **patent** costs, TTBD does not seek extensive foreign **patent** coverage or follow-on **patent** applications on a **technology**. That said, TTBD has established an internal Patent Group that internally files and prosecutes OHSU **patent** applications, manages outside **patent** counsel, and oversees **patent** strategy for OHSU **technologies**.

Figure 3.1. Patent Process



PROVISIONAL APPLICATION

Once it is decided that a **technology** should have **patent** protection for commercialization, the first step in the **patent** process is often the filing of a United States **provisional patent application**. To produce a high-quality provisional **patent** application, the Patent Group or outside **patent** counsel must be provided with at least two weeks and preferably a month of lead-time. The lead-time allows the Patent Group to compare the disclosure with the **prior art** and write a complete specification and commercially valuable **claims** defining the **invention**. The **provisional application** must be followed by a regular **patent** application such as a **Patent Cooperation Treaty** (PCT) application, United States non-**provisional application**, or other national (foreign) application within one year of the filing of the **provisional application**, or the priority rights of the **provisional application** expire.

PCT APPLICATION

Often, the next **patent** application resulting from the **provisional application** is a PCT application. A single PCT application is the equivalent of individual filings in all 146 member countries of the PCT. The purpose of the PCT application is to delay payment of the filing fees in individual countries for an additional 18 months following the filing. This allows additional time to assess the market for the **invention** before the major costs of foreign filing and prosecution (i.e., examination) are incurred.

NATIONAL APPLICATIONS

Thirty months from the filing of the first (**provisional**) **patent** application and 18 months from the filing of the PCT application, the PCT application must enter what is called national phase or the **patent** application goes abandoned. At this phase, filing fees that were delayed by the filing of the PCT application are due. Also at national phase, countries are selected. Entry into countries outside of the U.S. requires a substantial cost investment and therefore a highly compelling reason must exist to file in those countries. Costs are high because outside foreign counsel must be used (**patent** attorneys and agents may practice only in their home countries), many countries require translations of **patent** documents from English to the native language, **claims** in the **patent** must be customized to adjust to country specific **patent** laws, and each country requires separate filing fees. Initial filing in a typical set of countries (U.S., Europe, Canada, Japan, China, India, South Africa,) may be as much as $70,000 in the first year, $100,000 in the second year, and $150,000 in the third, fourth and fifth years.

PATENT PROSECUTION

Patent prosecution is in effect a negotiation between a **patent** examiner and a **patent** applicant to determine the scope of the **patent** grant. The scope of a **patent** grant is encompassed by the allowed **claims** of the **patent**. The allowed **claims** may then be enforced on **infringer**s in the country in which they are allowed. As discussed above, the **patent** holder may prevent the **infringer** from practicing the **invention** and/or the **patent** holder may obtain damages resulting from the **infringement**. If there are no **patent claims** in a particular country then the **invention** is in the public domain in that country and may be practiced freely. However, a product that **infringes** the **claim** may not be imported into a country in which a **patent** is in force.

RESTRICTION REQUIREMENT

Often the initial response from a **patent** office (up to three years following nationalization in a specific country) is a requirement for restriction. In most countries, a **patent** must describe a single **invention**. If the examiner determines that the **patent** application **claims** multiple **inventions**, the applicant receives a requirement for restriction.

In the restriction requirement, the purpose is to ask the applicant to pick a single **invention** to pursue in the current application. The applicant then may pursue the other **invention**s not selected at that time in one or more **divisional applications** at a later date, with all given identical priority dates to the original application. The later filed applications have the same priority date because they were, in effect, filed at the same time as the original application. Such **divisional applications** must be filed while the original application or a later application claiming priority to it is still pending (i.e., not yet issued or abandoned).

In the U.S., the restriction requirement can often include a requirement for species election (in biotechnology/pharmaceutical space) or apparatus vs. method election (in device/software space). For example, the species election can occur when a **claim** includes a number of disparate elements – a situation that is often present in method of treatment **claims** in which the use of the compound to treat a number of different diseases is claimed in a single **claim**. The examiner requires the applicant to pick one of the diseases as the elected species. This works to the benefit of the applicant because if the examiner finds any one of the diseases in the **prior art**, the examiner must reject the entire claim. By electing the species (preferably the disease the applicant cares the most about), the applicant signals to the examiner which species is the most interesting, and a secondary search can be carried out just on that species. In that way, the applicant gets more information about the lead **invention**.

OFFICE ACTION

An office action is a response from the **patent** examiner that officially allows or rejects **claims** in a **patent** application. **Claims** may be rejected on the basis of novelty, obviousness, enablement, or other legal reasons. Often, all **claims** in the **patent** application are rejected in the first office action. In the U.S., the applicant may respond to the office action within three months of its mailing date and incur no late fees. The applicant must respond to the office action within six months of mailing of the office action or the **patent** application goes abandoned.

The goal of the response to the office action is to put the rejected **claims** in condition for allowance by overcoming the reasons for rejections. There are many strategies for doing this and these may be employed alone or in combination with one another. These strategies can include the following actions:

1) Amend the **claims**. Commonly, narrowing the scope of the **claims** can overcome the rejection. However, one must be careful that the **claims** not be narrowed so much that they are no longer commercially viable (i.e., the only **infringer** is the end user rather than a manufacturer, **infringement** cannot be detected, or public domain workarounds are easily available).

2) Provide evidence of non-obviousness or enablement. As described in detail above, one way out of an obviousness rejection is to provide evidence of secondary factors of non-obviousness. In addition, evidence that the specification does enable one skiled in the art to make and use the **invention** can be introduced.

3) Provide arguments that the examiner improperly applied the **prior art** or **patent** law. This strategy does not commonly work without also amending **claims** and should preferably not be applied unless there is enough commercial value to the application that an appeal of the examiner's decision is warranted (as an appeal will likely ultimately be necessary). This kind of response to an office action will usually result in the next office action being a final office action.

The following description is the procedure in the U.S., but many other countries are similar: The first office action from the examiner is termed a non-final office action. If the applicant responds and the examiner sustains the same rejection on the same basis, then the next office action is a final office action. When the applicant responds to the final office action, the applicant must convince the examiner that the **claims** have been put into condition for allowance, but this is rarely successful and cannot present new arguments. If the examiner continues to reject the **claims** after the reply to the final office action, the applicant's only options are to a) appeal the decision to a board within the **patent** office or b) file a **Request for Continued Examination** (RCE). These appeals are usually not successful.

CONTINUING APPLICATIONS

Continuing applications are additional **patent** applications that result from the same (or a similar) specification with different **claims**. These consist of **Continuation Applications**, **Divisional Applications**, and **Continuation-in-Part Applications**.

ALLOWANCE AND ISSUANCE

When all **claims** in a **patent** are in condition for allowance (by amendment of **claims** or deletion of rejected **claims**), the examiner sends a notice of allowance. The **patent** holder then pays an issue fee and the result is an issued **patent**. This **patent** is the grant of the exclusive right to stop someone from **infringing** the **patent**.

COPYRIGHTS

Copyrighted works may be registered in the U.S. for a small fee. The main benefit of **copyright** registration is to allow the **copyright** holder to collect damages in a **copyright infringement** suit in the U.S. However, U.S. copyright registration is not required in order to commercialize or license copyright materials. International **copyrights** are obtained immediately upon fixing of the work in a tangible medium of expression (saving a manuscript draft or source code on a hard drive, printing of a photograph, etc.) Registration is not required in countries outside the U.S.

SOFTWARE

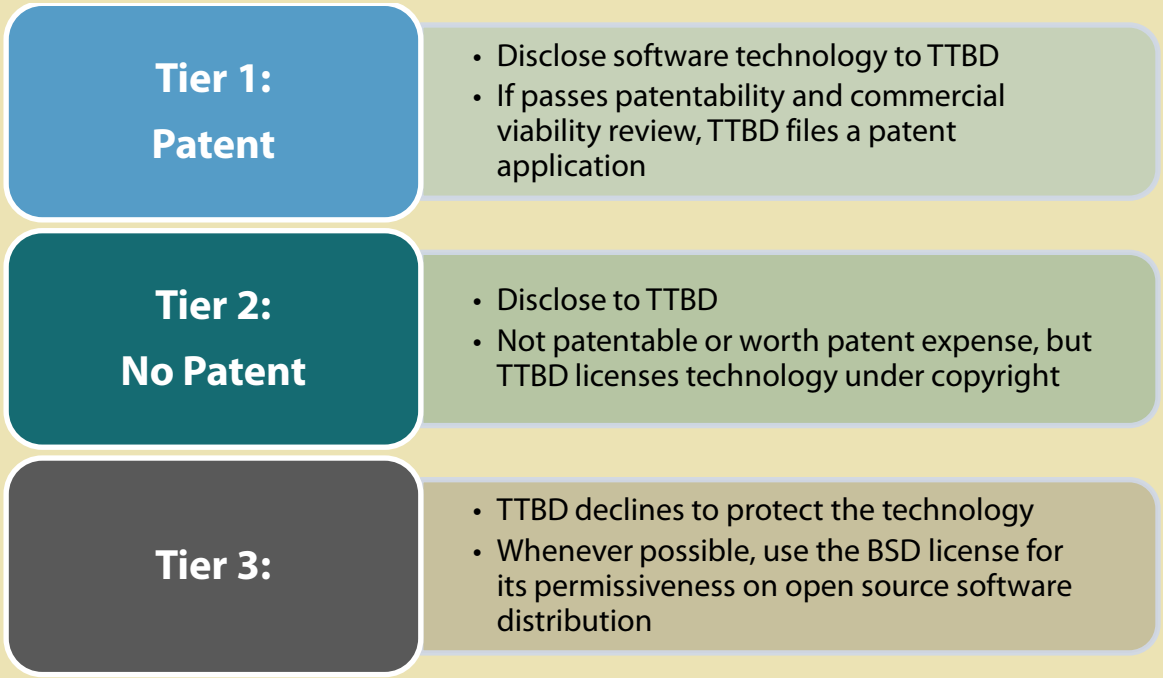
Software may be the subject of **copyright** and **patent** rights. The **copyright** is generally drawn to the source code of a computer program. The operative rights granted in **copyrights** to software are the rights to exclude others from copying or making derivative works of the source code (i.e., the original work in tangible fixed form in which it is set down).

The decision on whether to rely on **copyright** only or **copyright** and **patent** rights in the software space depends on the commercial value and what we are truly trying to protect. When the value is in the content and not the **technology** (algorithm) delivering the content, the protection will be narrow or easy to design around, and/or the **patent** would be non-strategic to any business, then relying on **copyright** rights alone can make sense. If there is big dollar potential, then a dual **copyright** and **patent** strategy may be desirable. If there is a lower dollar potential, then a **copyright**-only strategy might be best.

Copyright can be used to prevent total duplication of a software program, as well as copying of a portion of code. **Copyright** does not prevent (protect against) reverse engineering. It only protects the expression of the software **invention** (the code itself), not the **invention** itself. In summary, **copyright** will not prevent the creation of a competing program that utilizes the same idea (algorithm) as the existing program. A **patent** on the other hand may prevent others from utilizing a certain algorithm without permission and/or creating software programs that function in a certain way.

Commonly, technical journals ask that authors assign their **copyright** in manuscripts published in a journal to the journal. The authors may make these assignments to the journal without the involvement of TTBD.

Figure 3.2. Stratification of OHSU Software



TRADE SECRETS/KNOW-HOW

To enforce a **trade secret** one must show it has a **trade secret** policy, and OHSU has no such policy or enforcement of **trade secret** protection. NDAs provide little if any protection when it comes to protecting a **trade secret.** For these reasons, OHSU does not typically maintain trade secrets.

Know-How is a concept that is somewhat independent of the other forms of IP protection. **Know-How** may be the subject of **patent** protection or not. **Know-How** may be commercialized in a number of ways: through **sponsored research agreements** (SRAs), through **research service agreements** (RSAs), as add-ons to **patent** licenses, as consulting agreements, or as a license to a **startup** company.

Over fiscal years 2010-2012...

TTBD has averaged 39 patent application filings on new inventions each year.

TTBD has averaged nearly 150 total patent application filings each year.

TTBD has averaged 18 issued U.S. patents each year.

PATENT FAQs

Does OHSU initiate or continue patenting a technology without an identified licensee?

Often OHSU accepts the risk of filing a **patent** application before a **licensee** has been identified. After OHSU's rights have been licensed to a **licensee**, the **licensee** generally reimburses OHSU for the patenting expenses. At times, TTBD must decline further **patent** prosecution after a reasonable period of attempting to identify a **licensee** (or if it is determined that reasonable **patent claims** cannot be obtained).

Who is responsible for patenting?

TTBD is responsible for patenting OHSU **inventions**. The Patent Group drafts, files and prosecute **patents** internally or may contract with outside **patent** counsel. **Inventor**s work with the TTBD Patent Group and external **patent** counsel (if applicable) in drafting the **patent** applications and responses to worldwide **patent** offices. No OHSU employee is to file his or her own **patent** applications where the subject matter of the **patent** application arises from the work the employee was hired to do at OHSU.

What is the role of each inventor in the patenting process?

The role of each **inventor** is to work with TTBD and respond to TTBD and outside **patent** counsel requests for input and/or information. While some aspects of the **patent** process may require significant participation by each of the **inventors**, TTBD strives to make efficient use of the **inventor**s' time. Also, the **inventors** must keep TTBD informed of upcoming publications or interactions with companies related to the IP.

Can inventors publish the results of their research and still protect the commercial value of IP they develop or create?

Yes, but since **patent** rights are affected by these activities, it is best to submit an **IP Disclosure Form** well before communicating or disclosing the **invention** to people who are not OHSU employees. **Inventor**s must inform TTBD of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/thesis, publication, or other public presentation that includes any aspect of the **invention**.

What is the America Invents Act (AIA) and how does that relate to patents at OHSU?

The America Invents Act is the biggest change in U.S. Patent Law since 1952, and there are many changes to the law. Most of the changes are invisible to OHSU employees outside of the Patent Group and TTBD. The most important rule change related to research at OHSU involves the change from a "First-to-Invent" to a "First-Inventor-to-File" approach. Prior to March 2013: First-to-Invent - A **prior art** reference dated less than one year prior to the filing date of a **patent** application may be overcome by producing evidence that the **inventors** had actually conceived of the **invention** prior to the date of the **prior art** reference. In the case of an earlier filed **patent** application, the result is an interference proceeding between the two parties seeking **patent** rights in which each side shows evidence that it was the first to conceive the **invention**. After March 2013: First-Inventor-to-File - For **patent** applications filed after March 16, 2013, it will no longer be possible to overcome a **prior art** reference by showing that the inventors were the first to invent. The initial priority date of the patent application is all that matters. If the priority date is after the reference, the reference may be used as prior art to limit the **claims**. There are two notable exceptions: 1) A **public disclosure** of the **invention** published by an entity's own group dated less than one year prior to the filing date of the **inventors patent** application may not be used as **prior art** to the **inventor's invention**. It is important to note that **the full extent of this grace period has yet to be decided**. 2) A showing that a prior filed **patent** or **prior art** reference disclosed by another was derived from information that the other person received from the **inventors** will remove the reference as **prior art**.

Under the new First-Inventor-to-File regime, should OHSU be filing provisional applications early in the process?

No. What has not changed is the requirement that for **patent claims** to be valid, the **claims** must be enabled by the specification. As described above, the main test for enablement is whether a **person having ordinary skill in the art** would be able to make and use the claimed **invention** from the description given in the specification without undue experimentation. For a **patent claim** to have priority to a **provisional application**, the **claim** must be enabled at the time the **provisional application** was filed. With the new emphasis on filing date provided by the AIA, it is likely that it will be more important to have fully enabled **provisional application**s in the future.

BUSINESS DEVELOPMENT

The Business Development (BD) Group supports OHSU's commercialization mission of moving ideas from the research laboratories to the marketplace. To do so, BD works closely with the office of the Dean of the School of Medicine and the Office of the Vice President for Research, department chairs, as well as center and institute directors, to help develop strategies for corporate partnerships, engage **industry** in alliances, and participate in activities that explore new ways to implement OHSU's commercialization and strategic goals. These actions advance OHSU's commercial endeavors and ensure that OHSU's efforts to engage industry partners are streamlined, coordinated, and maximize outcomes for its partners and for OHSU faculty and staff.

PARTNERSHIP BUILDING

The BD Group serves as one of the liaisons between OHSU and the external partnering community (i.e., pharmaceutical companies, biotechnology companies, medical device companies, and other private companies), providing the bridge between the OHSU community and **industry** that is essential for the translation of research discoveries into services and products that meet critical social needs.

Commercialization strategies, activities, and goals vary, based on OHSU and an external partner's interests, needs, resources and opportunities. In order to develop a meaningful dialogue, the BD Group conducts preliminary background market research and initiates communications with **industry** representatives to ensure that BD understands **industry**'s current position. BD, in turn, educates **industry** about OHSU's strengths, assets and resources. These interactions often lead to **industry** visits where BD further explores the potential for a scientific collaboration.

BD also arranges strategic meetings between potential **industry** partners and researchers who have expertise in the **industry's** areas of interest. In some cases, **industry** partners contact BD looking for opportunities within specific areas. Alternatively, BD may introduce partnership opportunities to companies where BD sees the potential for a good fit (based on research BD regularly conducts to further identify OHSU researchers, expertise, and resources) that matches **industry** interests or that could be generally marketed as OHSU partnering opportunities. To do so, BD engages department heads and leads, interviews researchers, and searches databases and other resources.

FORMING COLLABORATIONS

Collaborations that may result from these meetings range from sponsored research projects with a single principal investigator (PI), to clinical trials, to large-scale product or device co-development partnerships. Although not every meeting results in a partnership, each time an **industry** partner visits, s/he becomes more familiar with OHSU's capabilities and strengths that may lead to a partnership at a later date. These visits build and strengthen OHSU's scientific and business relationships, increasing the likelihood that **industry** partners become strong advocates for OHSU.

Recent Strategic Development Activities

- Helped the Oregon Center for Aging and Technology (ORCATECH) and the Oregon National Primate Research Center (ONPRC) identify their commercial potential
- Worked closely with the OHSU Research Roadmap Committee, led by the Senior Associate Dean for the School of Medicine, to identify OHSU's overall strategic goals in asset commercialization

Databases and Resources to Identify OHSU Researchers for Partnering

- SciVal Research Expertise Locator*
- TTBD internal database
- PubMed
- Sponsored Projects Administration (SPA) data exports (includes grants and clinical trials)
- OHSU faculty webpages
- OHSU/other news releases

* http://www.ohsu.edu/xd/research/centers-institutes/octri/collaboration/collexis-expertise-locator.cfm

Once an **industry** partnership is established, BD works with the Technology Development and Licensing Group as well as the Industry and Academic Collaborations Group and others to ensure the partnerships are carried out. BD also helps manage the alliance throughout the course of the partnership.

INTERNAL OHSU EFFORTS

The BD Group plays a catalytic role in researcher interaction and community outreach. In addition to exploring external partnerships, BD also engages in internal OHSU programs to develop the programs' commercialization potential. BD has proactively engaged the OHSU research community (clinical and basic sciences) in creating interdisciplinary research consortiums in the areas of diabetes and obesity, pain, aging, and rare diseases. These consortia have brought scientists from different OHSU departments and disciplines— who were conducting independent research within similar subject areas—into contact with one another to share resources, apply for multi-investigator initiated National Institutes of Health or Department of Defense grants, and develop alliances with **industry**.

OUTREACH

The BD Group also represents OHSU in the community, participating in various professional networks, in profit and not-for-profit organizations, and with investors and local civic bodies. Through outreach and involvement, BD helps tap into community support for OHSU's business development activities and relationship building, thereby increasing awareness of TTBD's function and critical role in the economic development of Oregon.

Since BD spans various disciplines and areas and is engaged in a range of activities, the key to success for BD depends on BD's ability to work closely and collaboratively with groups both within and outside of OHSU, to serve as a liaison, and to build and maintain relationships with external partners (i.e., pharmaceutical companies, biotechnology firms, private companies, investors), internal stakeholders, and the larger community.

The BD activities outlined above are part of the overall TTBD mission to support the OHSU research community and promote an entrepreneurial culture.

Why would external companies want to partner with OHSU?

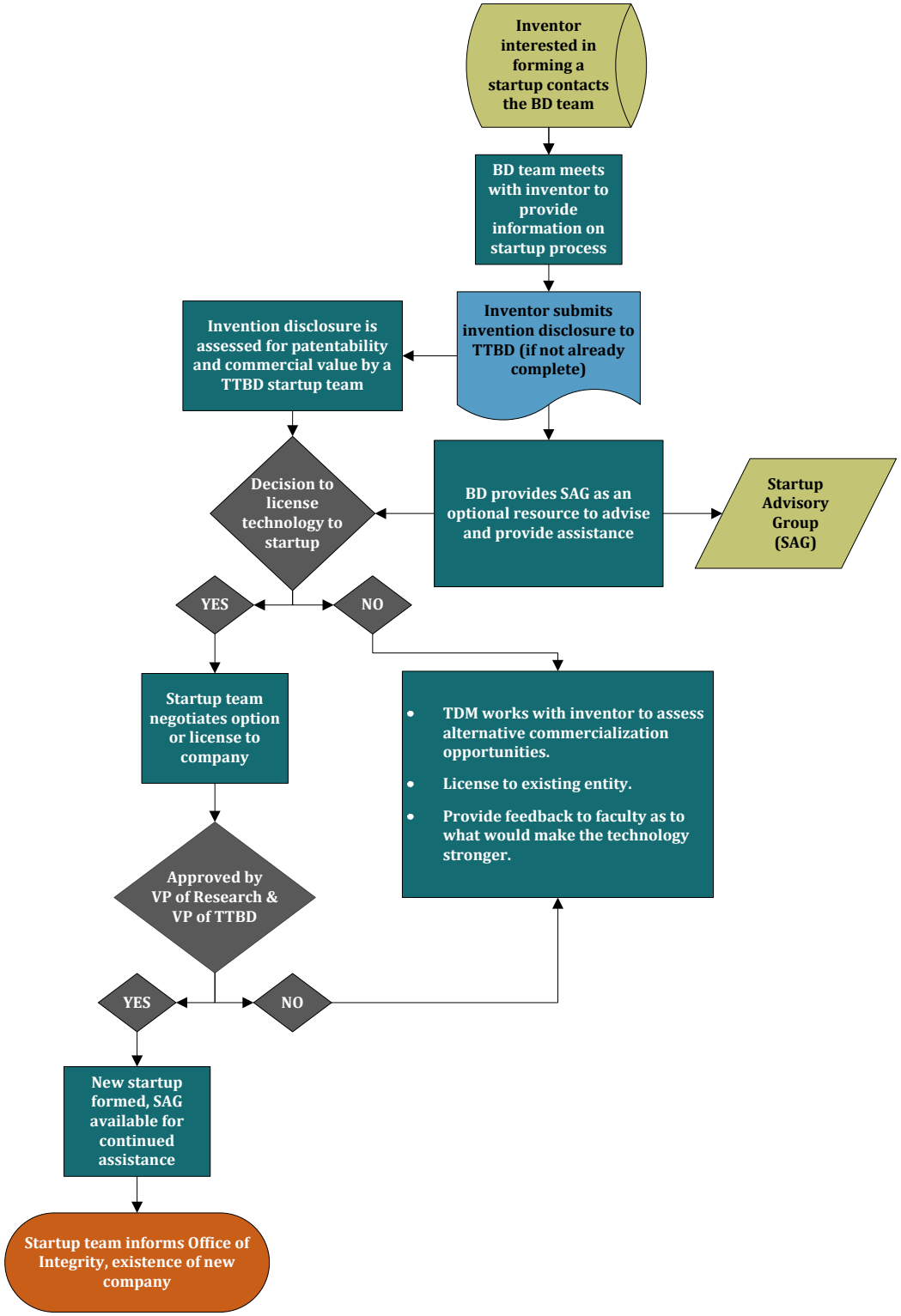
- To identify basic research breakthroughs that lead to new research and development (R&D) projects for the company
- To understand the biological mechanisms behind a drug or therapeutic effect
- To gain access to a clinical population unique to OHSU for device development testing
- To assess the safety or efficacy of a new therapeutic
- To identify new uses for old drugs
- To diversify their portfolio

STARTUP COMPANY FORMATION

BD also helps and supports OHSU employees who express interest in, or who are already engaged in, starting a company based on their research at OHSU. This important support role serves to ensure that faculty have the information and resources they need to start a company. BD provides direction and a step-by-step process to increase the likelihood of long-term success. BD manages the relationship between OHSU and the startup and tracks their evolving progress. BD also plays a critical role by interacting with the local business community of investors, entrepreneurs, and executives to provide outside resources and expertise as needed to help commercialization and startup prospects. In addition, BD has established a Startup Advisory Group (SAG) consisting of volunteer business professionals, advisors, consultants and entrepreneurs, who bring their entrepreneurial expertise and skills to mentor and assist the faculty with the startup process from the beginning to the launch a startup has been. The SAG offers startups valuable perspective and knowledge, and can help identify and vet appropriate financial and other resources.

A **startup** company is a new legal business entity that has licensed OHSU-owned IP. It is highly advised that OHSU employees who are considering starting their own company based on an **invention** conceived and developed at OHSU first submit an **IP Disclosure Form** to TTBD to initiate the process. Following review and analysis of an **IP Disclosure Form** by the Technology Development and Licensing Group, if the formation of a **startup** company based on the **technology** is an option, the TDM and BD work as a team to assist the **inventor**s. This assistance consists of guidance, resources, and tools necessary to enable the **inventor**s to launch a **startup** company. Further details on the **startup** process are described in TTBD's upcoming Startup Guide.

Figure 4.1. Startup Process



BUSINESS DEVELOPMENT FAQs

What should be done if a call or email is received from an industry representative interested in certain work with OHSU?

Begin by gathering as much information as possible about the **industry** representative's interest. Also, ask how the representative found out about the particular work (this can be helpful for the BD group in marketing OHSU's research). Get TTBD involved as soon as possible. Do not agree to anything or speak/write in detail about any unpublished work without a NDA in place. If there is uncertainty as to the existence of a NDA, assume there is no NDA.

How does BD know enough about the various projects on campus to identify research groups as potential matches for industry partners?

Because BD finds faculty matches through online resources/databases and by talking to department heads or people in the field, make sure that department heads and colleagues at OHSU know about all areas of work at OHSU and ensure that information is up-to-date on all faculty webpages, OHSU webpages, department webpages, SciVal experts, etc. BD also find matches by scouring information from PubMed, Sponsored Project Administration (SPA) data (clinical trials, externally sponsored research, etc.), and TTBD's internal databases. Additionally, if BD finds opportunities that may be available for a large group of people (i.e., an **industry** request for proposals), BD posts these on the Research News blog (http://www.ohsu.edu/blogs/researchnews/). Contact TTBD at any time to request a meeting or provide a brief overview of the work so TTBD can document it for later opportunities.

After hearing a talk at a national meeting, there is interest to develop a partnership with a biotechnology/pharmaceutical/medical device industry partner to leverage institutional access to clinical material(s). How can TTBD help?

TTBD has contacts in the biotechnology, pharmaceutical, and medical device industries and may be able to provide connections to the right people more quickly.

There was recently a call for projects/proposals from a biotechnology/pharmaceutical/medical device industry partner. How should one proceed in order to apply?

Work with the respective OHSU department on any budgetary issues, and connect with TTBD to ensure that the information shared in the application is protected and that the project being proposed is feasible under OHSU regulations and policies. TTBD also may be able to assist with the proposal in different ways, including helping find contacts at the **industry** partner to inform them of the proposal, or referring other OHSU resources that may benefit the proposal.

What should be expected when the BD Group has setup meetings with an industry representative?

Industry visits at OHSU require days of preparation. This allow us to provide to the industry OHSU's information, scientific work and the faculty expertise that are most relevant to their interest. The BD group always tries to have pre-visit conversation with industry partners to better understand their need so that the right OHSU colleagues are contacted well ahead of time. Participation by faculty at any industry meetings is voluntary. The BD group carefully considers the relevance, willingness and availability of the faculty before setting up any appointment and helps with providing the venue and the necessary equipments for presentations. Often faculty seek guidance from BD with presentation rehearsal for feedback. All presentations are preferably made in OHSU approved format and in OHSU power point template to maintain consistency. Most of the industry meetings unless indicated do not have a Non Disclosure Agreement (NDA), hence confidential or un-published information is not to be shared with the industry. BD group will always follow up with the industry contact for feedback and follow up action that is shared with the faculty.

What should be done if the formation of a startup company is being contemplated?

The first step is to submit an **IP Disclosure Form** to TTBD, if not already submitted. Work with the assigned TDM to ensure s/he understands the **invention**. Following analysis of the **invention**, the TDM works with the BD Group to help explain to the **inventor**s the **startup** process and all that is involved in starting a company.

How much time and effort does it take to form a startup company?

Starting a company requires a considerable amount of time and effort on the part of the founders and any others who may be involved. This is a decision that should not be taken lightly. Several factors determine exactly how much time and effort will be involved, such as each person's role with the company both before and after it has been formed. Each founder should have their supervisor's approval prior to becoming a founder of a new **startup** company, as becoming such may affect the time and effort devoted to OHSU job responsibilities.

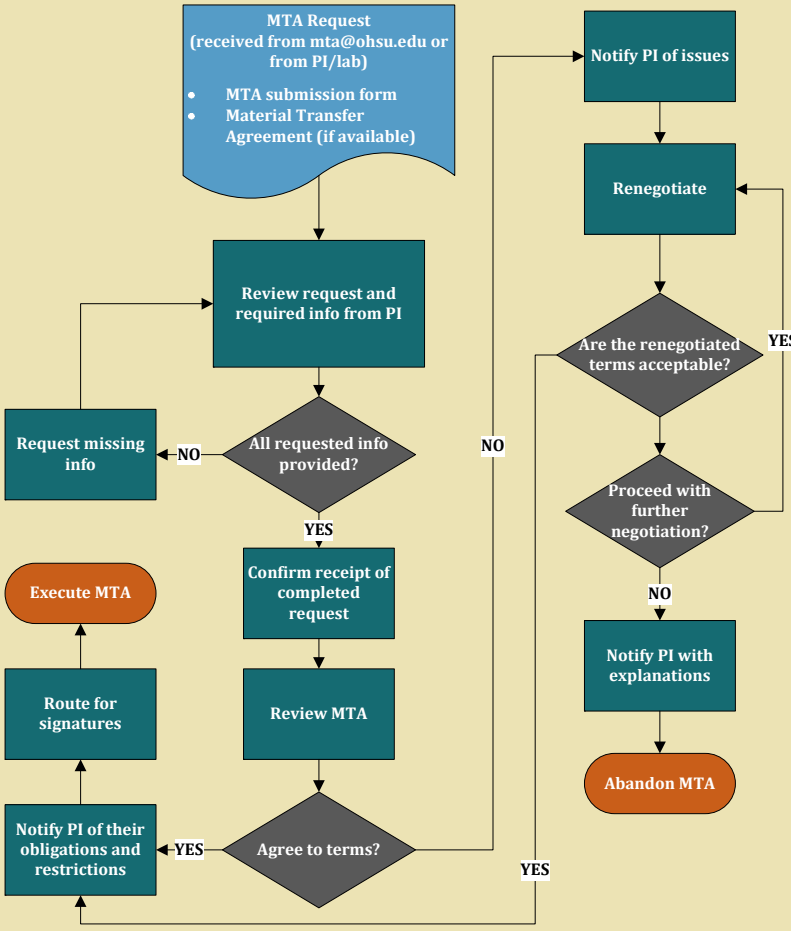
INDUSTRY & ACADEMIC COLLABORATIONS

Building successful collaborations and relationships between industry and academia rarely occurs without the exchange or receipt of information, tangible materials and sometimes funding. The Industry and Academic Collaborations Group, comprised of Agreements Officers (AOs), review and negotiate contracts governing the sharing of research materials and data, funding for industry sponsored preclinical or retrospective studies, preclinical research collaborations and the sharing of confidential and proprietary information. These contracts help define and preserve critical rights for the OHSU research community, including: i) the freedom to publish, ii) the freedom to use research results for future intellectual pursuits, iii) the freedom to stop research should unforeseen problems occur, iv) the receipt of adequate compensation for conducting industry sponsored research and v) the establishment of favorable guidelines for licensing intellectual property created through collaborative projects. This group works closely with the BD and the Technology Development and Licensing Groups, as well as other OHSU research administration departments including Research Grants and Contracts, Clinical Trials Office, Contracting Services Group, and Sponsored Projects Administration.

Over fiscal years 2010-2012, TTBD executed 465 MTAs on average each year.

MATERIAL TRANSFER AGREEMENTS (MTA)

Most parties are willing to share research materials as long as there is documentation of the terms and conditions under which such materials will be shared. The most common document used is a MTA. The terms and conditions in a MTA outline important general principals such as ownership rights of subsequent IP or **technology**, the right to publish or disclose research results, termination procedures, and what the parties can do should they have a grievance with each other. TTBD's primary objectives in reviewing and negotiating the terms of MTAs are to ensure that the MTAs do not affect future work by the investigator, are not contrary to funding requirements, and allow the investigator to freely publish the results of their work. IP rights can be endangered if materials are used without a proper MTA.



MTAs are required by most research organizations to memorialize the fact that the parties have advance notice of all obligations and restrictions concerning the use or receipt of research material prior to any actual exchange of material. It is typically the responsibility of the institution providing the material to initiate a MTA. The restrictions can be minimal or complicated and onerous. Regardless, TTBD works to help the OHSU community understand its obligations and to negotiate on behalf of OHSU so that the greatest academic freedoms are preserved.

MTAs clarify responsibilities such as who is liable should a material have unknown properties that are found to be harmful at a future time.

Figure 5.1. MTA Process

Over fiscal years 2010-2012, TTBD executed a total of 241 SRAs and RSAs which brought into OHSU over $31 million.

MTAs protect an investigator's or an institution's IP and ownership rights generated from the research results, especially when materials are received from **industry**. MTAs limit the manner in which a material can be used, to ensure that another party does not use the material for commercial purposes without taking a license to do so. It is important to remember that MTAs for materials coming into OHSU will often place additional obligations on research. TTBD can help work through these additional obligations.

A MTA that is signed only by an investigator is not a valid agreement. MTAs must be signed by an authorized official with the authority to bind the entire institution to the terms and provisions of the agreement. TTBD, through the office of the Vice President for Research, has the authority to sign MTAs. The investigator or head of the lab will often be asked to sign a "Read and Acknowledged" statement signifying that the he or she has read and understands the terms of the agreement.

INDUSTRY-SPONSORED RESEARCH AGREEMENTS (SRA) AND RESEARCH SERVICE AGREEMENTS (RSA)

Partnering with **industry** presents unique opportunities and challenges. Investigators at times seek ways outside of the government grant system to increase the stream of research funds into their labs. In the 2012 fiscal year alone, TTBD negotiated 12.8 million dollars of research support through **industry**-sponsored research. The TTBD Industry and Academic Collaborations Group works closely with investigators, department administrators and **industry** sponsors to complete the funding agreements, SRAs, and RSAs necessary for building and maintaining mutually beneficial **industry**/ academic relationships. TTBD staff is knowledgeable and experienced in negotiating and executing all of these types of agreements to reach mutually agreeable terms.

The process for completing a SRA or RSA may be brief or lengthy depending upon the complexity of the research program and the overall expectations of the parties. Investigators must be very mindful of the terms of SRAs and RSAs as they are usually far stricter than the terms found in federal, philanthropic or foundation grants.

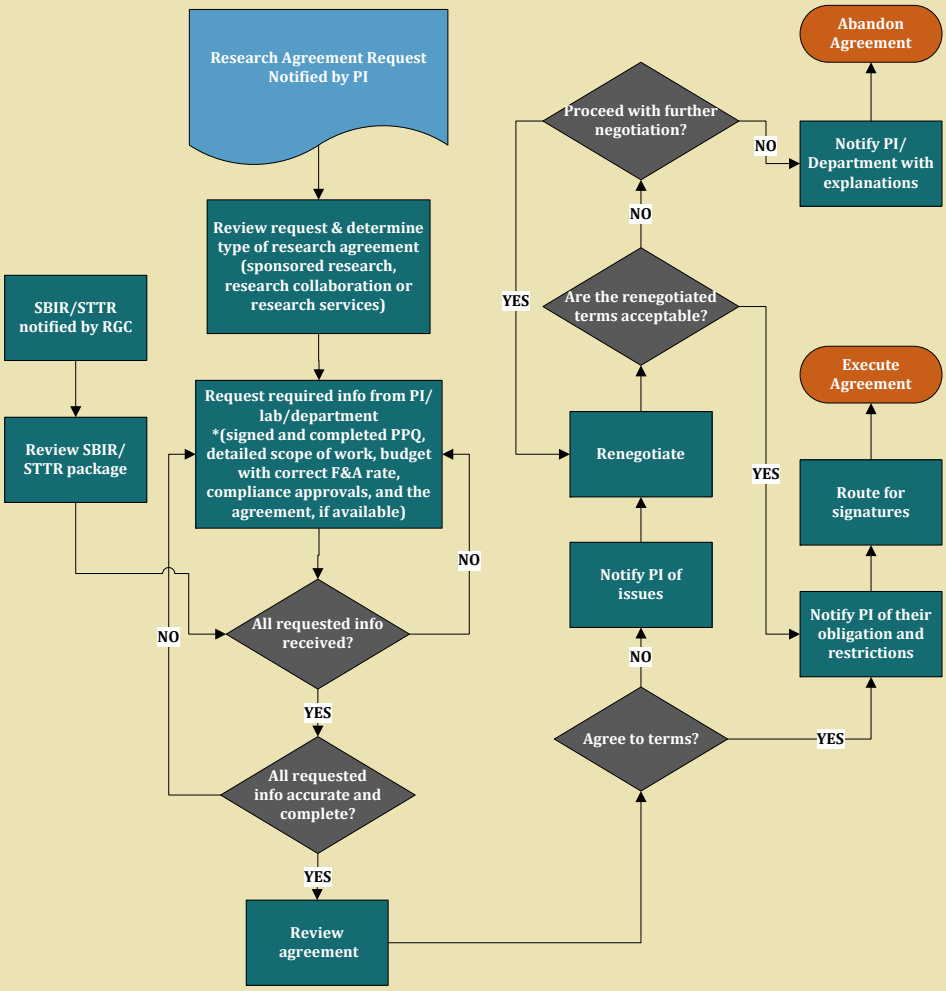


Figure 5.2. SRA Process

SRAs typically include terms governing the following: research **scope of work** (SOW) and budget (handled by the PI of the study and his/her Department), payment obligations and timing, ownership of IP, licensing of any IP developed through the project, and publication of results and terms for termination of the contract (all which are handled by TTBD).

RSAs typically include many of the same terms and conditions as SRAs, but typically do not address new IP. It is the expectation that if OHSU is performing a service, then no new IP will be developed. If OHSU employees contribute in any manner to development of the SOW for a project funded by an **industry** partner, then a RSA is not the appropriate agreement, but rather a SRA should be used. As with SRAs, the process for completion may be brief or lengthy.

One of the most time-consuming parts of the SRA or RSA process is the development of the research scope and appropriate budget. Investigators should work closely with their department support staff to create an initial budget, and then send the budget to the TTBD Industry and Academic Collaborations Group early so verification of the correct indirect cost rate occurs prior to any negotiations with an **industry** sponsor. For more information on indirect costs please contact Research Grants & Contracts.

Over fiscal years 2010-2012, TTBD entered into nearly 20 RCAs/year with industry partners.

RESEARCH COLLABORATION AGREEMENTS (RCA)

Joint research projects involving investigators at more than one institution are becoming more common as well as more complex. A **Research Collaboration Agreement** can help prevent any unnecessary future disputes between the parties by providing a framework around the collaboration. RCAs help each party understand upfront what roles, responsibilities, and obligations each have in performing the research. These agreements also help preserve the parties' rights in the research and eventual outcomes. RCAs between OHSU and collaborators, whether they are at other universities, non-profit research institutions, or **industry** partners, can facilitate a seamless flow of materials, information, data, publication, and other rights between two or more parties who are working together on a project.

CONFIDENTIALITY DISCLOSURE/ NON-DISCLOSURE AGREEMENTS

The sharing and receiving of unpublished information has upsides and downsides. Members of the OHSU community may want to share their unpublished information with close collaborators outside of OHSU or with **industry** that has shown an interest in certain work taking place at OHSU. Outside organizations and **industry** may also wish to share their own unpublished information with members of the OHSU community for a number of reasons. Under both of these circumstances, whether OHSU is providing or receiving unpublished information, a **Confidential Disclosure Agreement** (CDA) or NDA should be utilized.

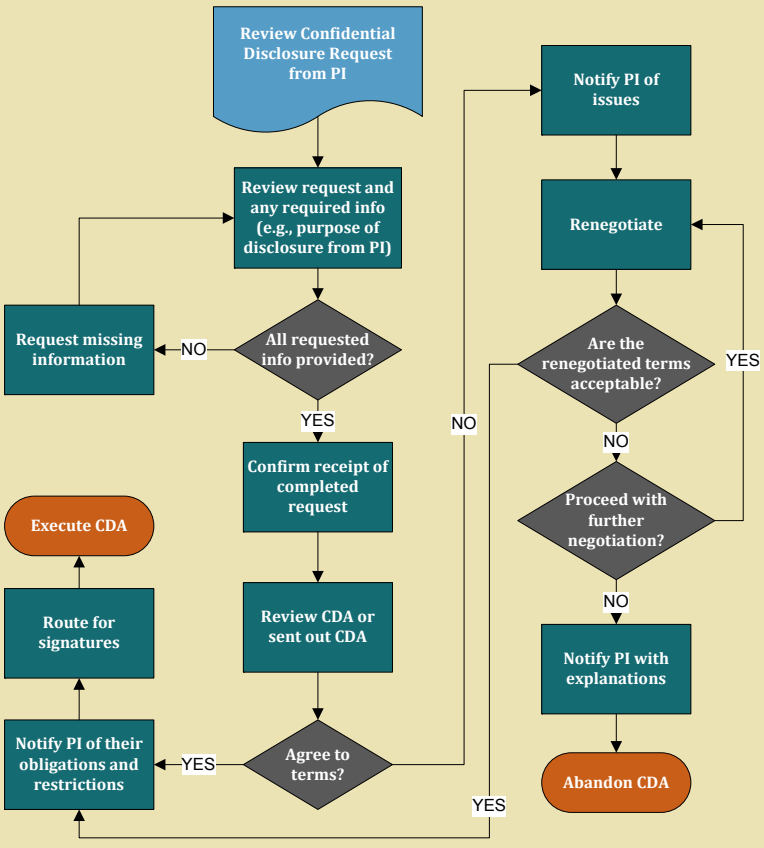


Figure 5.3. CDA/NDA Process

In fiscal year 2012, TTBD entered into nearly 150 CDAs.

CDAs/NDAs are used to protect the confidentiality of an **invention**, **technology** and any other non-publically disclosed, proprietary information. Non-OHSU individuals and **industry** representatives on campus are not covered under the general OHSU confidentiality policy and regulations. The only method of protecting proprietary OHSU information is to have the outside individual(s) sign a CDA or NDA. Discussing unpublished results or other non-public information with anyone outside of OHSU can result in a loss of certain IP rights (including **patent** rights).

Without a CDA/NDA in place, there is far less protection available to OHSU in regards to the disclosed information. TTBD must be contacted in order to preserve OHSU's rights if there are any thoughts or plans to disclose unpublished information.

Other organizations and **industry** representatives who are not OHSU employees may also require OHSU to sign a CDA/NDA prior to disclosing and discussing their own unpublished information with OHSU personnel. Only authorized OHSU officials can sign a CDA/NDA. If any OHSU employee is provided with a CDA/NDA by any outside party, the agreement must be reviewed and signed by an authorized official of OHSU.

ANATOMY OF AN AGREEMENT

Most contracts follow an accepted structure and can be broken apart into several key sections. Not every agreement will follow this description exactly, but most will follow a similar path regardless of whether they are a MTA, SRA or NDA. The initial paragraphs introduce the parties, their legal or business addresses and may discuss the background (called a preamble), introducing those involved and a description of the project or the materials being shared. Often this information is defined in the preamble and then described more fully as an exhibit to the actual agreement. Each subsequent section, paragraph, article, or subsection of a contract provides guidance on a particular issue, such as publication and ownership of results, definition of **invention**s, ownership of IP, indemnification, export control, a description of the research goals/protocol or a SOW, confidentiality terms, termination obligations, and contact information for legal notices. All sections taken together, along with any exhibits or attachments, comprise the complete understanding of the parties in any given agreement. The following details some the primary points and perspectives from both OHSU and **industry** on typical agreement terms.

SCOPE OF WORK/PROTOCOL

The SOW is sometimes brief when the agreement is a simple MTA where OHSU is obtaining **tangible materials** from another university. Sometimes the SOW is quite long and detailed. Regardless, the SOW must be sufficiently detailed so that each party can distinguish one particular project from other projects. There should be absolute clarity on what is being promised (project objectives), who is responsible for a particular aspect of the project, if applicable, when the results are to be delivered (i.e., timing and frequency of any reporting requirements) to whom the results are to be delivered, and an expected start and end date of the project.

Research that is subject to restrictions on publication may be considered a trade or business activity that is unrelated to the public purpose of OHSU, as required in OHSU's designation as a public non-profit corporation.

PUBLICATION

OHSU's mission as a public non-profit entity is to support the dissemination of scientific findings for the advancement of knowledge and for the improvement of health & wellbeing of the community. To meet this goal, TTBD strives to protect the academic freedom of OHSU employees to publish the results of their work in any contract negotiated on their behalf. **Industry**, however, needs to protect commercially valuable technologies, products, or processes and to do so it must control both the dissemination of information and the timing of any such disclosures. These competing needs often require negotiation of language that protects OHSU's rights to publish without unduly harming the commercial interests of **industry** partners, and sometimes even academic partners.

To balance these competing needs, the parties usually agree to have a review period where each party can request removal of their own **confidential information** that was shared during the project, and an additional period of delay for filing of **patent** applications or pursuit of appropriate protection for any **inventions** arising from the research. It may take negotiation to come to a timeframe that is acceptable to all parties. Delay in publication is not the same as allowing another party to approve whether results can be disclosed through publication. TTBD will not agree to allow an outside party to have any approval rights on whether or not OHSU can publish results and other information generated at OHSU.

OWNERSHIP OF IP

Research may or may not lead to the discovery of new IP. New IP at times requires the use of another party's pre-existing IP. Most SRAs, RSAs and CRAs, and some MTAs refer to any pre-existing IP (often referred to as Background IP). Any new IP that arises from carrying out the SOW can be handled in a number of different ways. TTBD's stance on ownership and rights to any new IP generated from the SOW is that ownership to any new IP should follow inventorship (determined by U.S. **patent** law). In other words, IP developed by a party belongs to that party, and the parties shall jointly own IP developed jointly by the parties. Therefore, if any OHSU employees are deemed **inventors** of any new IP under U.S. **patent** law, then OHSU will have an ownership stake in such new IP.

INDEMNIFICATION/WARRANTY

OHSU, as well as many public universities, cannot be responsible for the actions of others. OHSU can be responsible, though, for the acts or omissions of its employees, its conduct of the SOW, and its use of the results from a study. Agreements often ask one party to offer indemnification (payment of damages, losses, expenses, settling of third-party claims) that is triggered by a specific event or breach of a term of the agreement. For example, this can include the unauthorized use of materials provided under a MTA (i.e., use outside the SOW).

The freedom to publish is a requirement for protecting OHSU's FRE under export control regulations.

As an Oregon state-affiliated non-profit corporation, OHSU can only indemnify another party up to the limits provided by Oregon State Law. All agreements must state this explicitly if the choice of governing law and jurisdiction are outside of Oregon, or state it generally if Oregon choice of law and jurisdiction are preserved.

CONFIDENTIALITY

In the academic setting, the exchange of ideas, information and knowledge is encouraged. However, as discussed elsewhere in this guide there are frequent occasions when certain information must be kept in confidence. To balance the needs of both OHSU and its partners, the majority of agreements will address the sharing and receiving of another party's **confidential information**. Confidentiality sections will define what information is considered to be confidential, define who is the provider and who is the receiver of such **confidential information**, and delineate how such information can be used and shared with others. The obligations of confidentiality typically survive any expiration or early termination of the agreement for a set period of time.

*EXPORT CONTROL**

As a non-profit research institution and teaching hospital that engages in sharing of research materials and information, OHSU is subject to compliance with the U.S. Export Laws and Regulations and exempt from regulations in specific cases due to the **Fundamental Research Exclusion** (FRE). The two government agencies that oversee most of the laws applicable to exporting goods in the U.S. are the U.S. Department of Commerce and the U.S. Department of State. The majority of research conducted at OHSU is considered basic and/or applied research in science or engineering that results in broad publication of results or information disseminated into the public domain. This ensures that the FRE can be applied. When sponsors of research or industry partners restrict publication by requiring approval of research results, OHSU's FRE can be compromised requiring OHSU to take additional steps to secure an export license from the government. All CDAs and NDAs by their nature restrict the dissemination of data and/or other information. This is why TTBD asks that specific language be included in each to address the need for export control regulations. It is important that contractual relationships between OHSU and industry partners recognize and respect obligations and/or exemptions permitted under export regulations.

EXPIRATION/TERMINATION

All agreements should have a time frame for their existence and then should expire. Agreements can also terminate early for a variety of reasons prior to the set expiration date. If one party determines that it desires to terminate an agreement early, and it has the ability to do so under the terms of the agreement, most agreements have some mechanism for initiating early termination. Upon any expiration or early termination, most agreements have a delineation of the rights and responsibilities of the parties following such expiration or termination. In MTAs, this may require the return of transferred **tangible materials** or their destruction. In SRAs and RSAs, this may require a submission of all data and other information generated under the SOW to the other party. In CDAs/NDAs, this may require a return of the other party's **confidential information**. Further, just because an agreement has terminated or expired does not mean that certain clauses of the agreement are no longer in effect. As mentioned above, even upon expiration or termination there still may be requirements to keep certain information of the other party in confidence for several years thereafter.

**For more information on Export Control, go to www.ohsu.edu/xd/education/office-of-export-controls/about.cfm*

INDUSTRY AND ACADEMIC COLLABORATIONS FAQs

How long will it take to process a MTA?

All reasonable efforts are made to keep the amount of time to a minimum to complete every MTA. The amount of time for completing any MTA will vary depending on the number of MTAs in process at the time a new MTA is initiated, response time of the other organization, and the need for negotiating provisions in the MTA. It is important to plan ahead as some MTAs take just a few days to review, process and execute, while others can take weeks to months.

Can materials received under a MTA with another party be further shared with other laboratories within OHSU?

Usually not. Whether material that has not been developed at OHSU can be shared with other laboratories will depend on the MTA under which the material was obtained. Most MTAs require that the material provided will not be shared with other laboratories, including other laboratories within OHSU.

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

The SRA should specify the IP rights of the sponsor. OHSU generally retains ownership of the **patent** rights and other IP resulting from sponsored research. However, due to the sponsor's support of the study, the sponsor may have rights to obtain a license to the defined and expected outcomes of the research. Often, SRAs allow the sponsor a limited time to negotiate a license for any **patent** or other IP rights developed as the result of the research. Even so, the sponsor generally does not have contractual rights to discoveries that are clearly outside of the SOW. It is therefore important to define the SOW accurately within a research agreement.

An industry partner approaches an OHSU researcher to perform some work in collaboration with them. The industry partner is providing materials, but they are not providing any funding. Should this be a MTA or RCA?

It depends on the full nature of the interaction with the **industry** partner. A MTA would be appropriate if the materials are transferred and OHSU is the only party doing the research and providing copies of the results to the **industry** partner. A RCA would be appropriate if both OHSU and the **industry** partner are doing collective research that is beneficial to one another and there is a back-and-forth sharing of materials, data, and other information.

Would a RCA be a good idea for a research consortium?

Yes. A research consortium, typically involving several parties, would be an ideal situation to utilize a RCA.

What should be done if a CDA/NDA is received from an outside party?

If a CDA/NDA is received from an outside party, forward it to the TTBD Industry and Academic Collaborations Group for review of the terms and signature on behalf of OHSU.

An outside party is unwilling to sign a CDA/NDA. Can OHSU employees still speak with this party?

Yes, OHSU employees can still talk with them, but any information that has not been previously disclosed publicly should NOT be talked about. Some **industry** representatives and others outside OHSU may be unwilling to sign a CDA/NDA. This is not uncommon, but it should be remembered in these situations that the only information to be shared should be that which has already been published or previously presented outside of OHSU.

ADMINISTRATIVE SERVICES

The group supporting all other groups within TTBD is the Administrative Services Group. This group performs all **invention** reporting responsibilities to the government as well as **royalty income** distributions as required by OHSU policy. The group also provides several other general administrative tasks for TTBD.

GOVERNMENT INVENTION REPORTING

The **Bayh-Dole Act** allows universities and other non-profit institutions to have ownership rights to discoveries resulting from government-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 licensing preference to small businesses that demonstrate sufficient capability to develop **technologies** further, and sharing any resulting revenues with the **inventor**s of **technology**. The **Bayh-Dole Act** is credited with stimulating interest in technology transfer activities and generating increased research, commercialization, educational opportunities, and economic development in the U.S.

As part of the **Bayh-Dole Act**, TTBD must report each potentially patentable **invention** that is developed at OHSU using government funding to the proper government agency. It is required that all **inventor**s complete the **IP Disclosure Form** in its entirety. The disclosure must have all **inventor**s listed, list all the government agencies and complete grant or contract numbers that funded the work, include a written description of the **invention** in technical detail, and must be signed by each **inventor**. Once TTBD has received the completed **IP Disclosure Form**, TTBD is required to report the **invention** to the appropriate funding government agencies within two months. **Inventor**s are required to notify TTBD when any additional government grants and contracts not previously listed on the initial **IP Disclosure Form** are used to further develop their **invention**. TTBD is responsible for completing all other government **invention** reporting activities, such as whether OHSU decides to elect title to each **invention** or return title to the government.

FINAL INVENTION STATEMENT AND CERTIFICATION

A final **invention** statement and certification is required to be completed and submitted as part of the closeout phase of the government funding process within ninety days after expiration or termination of the grant or award. It is extremely important that the correct grant or contract numbers are listed on the **IP Disclosure Form**, so that when such grant or contract has expired or been terminated, the appropriate final **invention** statement and certification can be submitted by TTBD. The final **invention** statement and certification informs the granting government agency that all **inventions** created under the grant or award have been properly reported under the government **invention** reporting process. When a government grant or contract is ready for closeout, the OHSU office of Sponsored Projects Administration notifies TTBD. TTBD checks TTBD's internal intellectual database to determine if any **inventions** were created using funding from the closing grant or award.

ROYALTY INCOME DISTRIBUTION

As a condition of employment or service to OHSU, all OHSU employees assign to OHSU all right, title and interest to IP created or developed at OHSU (see OHSU's **Intellectual Property and Royalty Distribution Policy at** https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/). In return, OHSU employees share in the **Net Royalty Income** pursuant to the **Intellectual Property and Royalty Distribution Policy**.

Net Royalty Income is distributed as follows:

- The **inventor**s receive 40% of the first $50,000, 35% of the next $50,000 and 30% of everything thereafter. This money is taxable income and will be reported on the IRS Form 1099.
- The remaining **Net Royalty Income** is divided equally between the **UNIT** within which the **inventor**s worked at the time of the creation of the **invention** and OHSU.

Prior to any royalty distribution for a particular **invention**, a **Royalty Sharing Agreement** must be entered into between the **inventor**s. Some examples of royalty distributions are as follows.

Simple Example:

$25,000 **Royalty Income** received under a **license agreement** with one **inventor** from the School of Medicine (one of OHSU's **UNITs**) for a technology that had incurred $10,000 of patent expenses.

$25,000 minus $10,000 of unreimbursed **patent** expenses = $15,000 **Net Royalty Income**

Inventor share = 40% of $15,000 = $6,000

UNIT share = 30% of $15,000 = $4,500

OHSU share = 30% of $15,000 = $4,500

Complex Example:

$25,000 **Royalty Income** received under a **license agreement** with three **inventor**s from two OHSU **UNITs** (School of Medicine and School of Nursing), with two **inventor**s from SOM and one **inventor** from SON for a technology that had incurred $10,000 of patent expenses. The three **inventor**s have agreed to share the **inventor** share equally under a **Royalty Sharing Agreement**.

$25,000 minus $10,000 unreimbursed **patent** expenses = $15,000 **Net Royalty Income**

Inventor share = 40% of $15,000 = $6,000 split equally between three **inventor**s = $2,000 each.

UNIT share = 30% of $15,000 = $4,500 split between two **UNITs** per **inventor** in each of these **UNITs**. SOM receives $3,000 for the two **inventor**s in SOM, and SON receives $1,500 for the one **inventor** in SON.

OHSU share = 30% of $15,000 = $4,500

Over fiscal years 2010-2012, TTBD distributed to UNITs *and inventors roughly 60% of all Royalty Income received.*

TTBD is not responsible for distributing any **Royalty Income** directly to OHSU departments under the current **Intellectual Property and Royalty Distribution Policy**. **Inventors** should work with their department chairs to determine if any of the **UNIT** share will be shared with the department and/or with the **inventor's** laboratory.

ADMINISTRATIVE SERVICES FAQs

Why can't the PI submit their own final invention statement and certification?

Submission of the final **invention** statement and certification is an OHSU obligation that resides with TTBD. An authorized official of OHSU must sign such statement and certification. PIs do not have such authority.

What happens to an inventor's share of Net Royalty Income once s/he leaves OHSU?

The **inventor** will continue to receive their share of the **Net Royalty Income**. However, it is up to such **inventor** to keep TTBD informed of any mailing address changes.

Can an inventor waive their share of Net Royalty Income to someone else or their department?

Any special situation where an **inventor** wishes to waive their share of **Net Royalty Income** will be addressed on a case-by-case basis and approval sought by TTBD from OHSU's Vice President for Research.

OUTSIDE OF TTBD PURVIEW

There is quite a lot that the different groups within TTBD do to assist the OHSU community. However, there are several items that TTBD is often contacted about which it does not handle. The following is a short list of some of the most common items TTBD is asked about but unfortunately fall outside of its role.

CONSULTING AGREEMENTS

TTBD does not negotiate or review consulting agreements. TTBD is available to provide informal advice on how a consulting agreement may relate to OHSU IP. Anyone who is asked to enter into a consulting agreement with an outside party is strongly encouraged to consult with or hire an attorney to represent s/he personally in the review and negotiation of all such consulting agreements in accordance with the investigator's Departmental policies.

CLINICAL TRIALS AND CLINICAL TRIAL AGREEMENTS

TTBD does not handle clinical trials or clinical trial agreements. Clinical trials involving humans are either handled by the OHSU Clinical Trials Office or by OHSU Research Grants & Contracts for those PI-initiated trials funded by the government.

PURCHASING AGREEMENTS

TTBD does not negotiate or review any agreement that has as the sole purpose the purchase of outside equipment, software or other materials.

EQUIPMENT LOAN AGREEMENTS

TTBD does not negotiate or review agreements that have the sole purpose of obtaining equipment from an outside party for minimal or reduced cost.

FOOD AND DRUG ADMINISTRATION APPROVAL

While many people in TTBD are knowledgeable of the steps involved in Food and Drug Administration (FDA) approval process for diagnostics, therapeutics and medical devices, TTBD does not assist or advise with respect to the FDA approval process.

CONCLUSION

TTBD is present to serve the entire OHSU community, from researchers to clinicians to hospital staff to students to facilities personnel. TTBD hopes the readers of this guide have found it helpful in answering questions about the roles and responsibilities of TTBD, what TTBD does and why TTBD does certain things, how OHSU employees can access and utilize TTBD services and work with TTBD, and how TTBD can assist the OHSU community further. If there are any questions about anything mentioned in this guide or anything that was not covered related to the functions of TTBD, please do not hesitate to contact TTBD at any time. Thank you.

GLOSSARY

Agreements Officers (AOs): TTBD employees in the **Industry** and Academic Collaborations Group who review and negotiate a variety of contracts and other agreements including MTAs, SRAs, RSAs, CDAs and NDAs.

American Invents Act (AIA): The Leahy-Smith America Invents Act is patent reform act passed by Congress and signed by President Obama on September 16, 2011. The most significant changes were to the definitions of prior art and the implementation of a "first inventor to file" system rather than a "first to invent" system.

Bayh-Dole Act: US legislation dealing with IP arising from US federal government-funded research. Adopted in 1980, the Bayh-Dole Act is codified in 35 U.S.C § 200-212, and implemented by 37 C.F.R. 401. Among other things, it gave US universities, small businesses and non-profits control of their inventions and other IP that results from US federal funding. https://s-edison.info.nih.gov/iEdison/37CFR401.jsp

Claims: Define the limits of a patent owner's patent rights in a patent application, just as the borders of a piece of property define the limits of a landowner's rights. With the subject of claims, it is important to understand the types of claim structures and what they mean. System (apparatus) claims are tied directly to a device and describe an invention in terms of its components. Method claims are a series of actions that are performed to accomplish a result. Composition claims may include a chemical structure or formula, a biological sequence, or components of a mixture.

Confidential Disclosure Agreement (CDA): A legal contract between two or more parties that outlines confidential material, knowledge, or information that the parties (one or both) wish to share with one another for certain purposes, but wish to restrict access to, or by, third parties. CDA is synonymous with NDA.

Confidential Information: Privileged communication that is not public knowledge shared by one party to another for furthering certain purposes. The party receiving such confidential information is generally prohibited from sharing it with others and making unauthorized uses of the information. It is often referred to as "proprietary information."

Continuation Application: A patent application that has the same specification as a parent (original) patent application, but pursues different claims. The difference between a continuation application and a divisional application is that the applicant elects a continuation, whereas a divisional is elected by the applicant in response to being required to do so by the patent examiner. Generally, continuation applications are elected to maintain a pending case in the US for an invention that will or currently encompasses a marketed product. The claims of the continuation can then focus more on the current product version on the market or, potentially, an infringing product (assuming there is adequate support for such in the original patent application description/specification).

Continuation-in-Part (CIP) Application: A patent application that has the same specification as a parent (original) application and further includes new information that provides support for the enablement of the new claims. These typically cover improvements to the original invention. Since 1995, CIPs are only filed in rare situations. In most cases, it is better to file a new application on the improvement. That way, if the improvement is found to be separately patentable, it will have an extended term relative to that of a CIP.

Copyright: A copyright is the right to exclude others from copying, distributing, publicly performing, or making derivatives of creative works such as journal manuscripts, books, teaching materials, photographs, audio/video recordings, graphical designs, software, or any arrangement thereof.

Divisional Application: A patent application that has the same specification as a parent (original) application and will retain the parent's filing date, but is filed in response to a lack of unity of invention. If the parent application describes more than one invention, the applicant is required to split the parent into one or more divisional applications each claiming only a single invention.

Enablement: For an invention to be patented, the invention must be described sufficiently in the specification of the patent document that a person having ordinary skill in the art to which the invention pertains can make and use the invention. If the invention is sufficiently described, the invention is enabled by the specification. In addition to enablement is the written description requirement which requires that the specification show that the applicant is "in possession" of the invention and not merely discussing possible future implications of a scientific result.

Fundamental Research Exclusion (FRE): A protected category for institutions of higher education and research (including OHSU) under export controls. However, OHSU is required to confirm that its activity falls within these exemptions. Most, but not all, activity at OHSU is considered "fundamental research" and does not have restrictions on publications and therefore falls under the FRE from export controls. However, some OHSU research may not be considered "fundamental research" if OHSU or its researchers accept (at the request, for example, of an industry sponsor) restrictions on publication of scientific and technical information resulting from a particular project or activity. Scientific and technical information resulting from the research will nonetheless qualify as fundamental research once all such restrictions have expired or have been removed.

Industry: Any for-profit organization, or any organization whose operations function similarly to a for-profit organization, such as a pharmaceutical, biotechnology or medical device company.

Infringement/Infringer: Anyone who makes, uses, or sells an invention described by a claim of an issued patent without the permission of the patent owner. Infringers may be liable to the patent owner for damages. Such action by an infringer is referred to as infringement.

Intangible Assets: Any asset that is not physical in nature (it cannot be touched). Patents, trademarks, copyrights, business methods, and brand recognition are all common intangible assets.

Intellectual Property (IP): Includes inventions and/or materials that may be protected under patent, trademark and/or copyright laws, and sometimes by contract. Trade secret protection represents another form of intellectual property, but no formal protection/filing is sought under trade secret law.

IP Disclosure Form: TTBD's Intellectual Property Disclosure Form used to disclose any new invention to TTBD. This form can be found at http://www.ohsu.edu/xd/research/techtransfer/

Intellectual Property and Royalty Distribution Policy: OHSU Policy No. 04-50-001 found in Chapter 4 "Research Services and Intellectual Property" of the OHSU Policy Manual. This policy can be found at: https://o2.ohsu.edu/policies-and-compliance/ohsu-policy-manual/

Inter-Institutional Agreement (IIA): Describe the terms under which two or more universities or other institutions will collaborate to market, license and share in the revenues that may be received from licensing jointly owned IP. These agreements also describe how that parties will make patenting or other decisions related to protection of the jointly owned IP, including how any costs of securing such protection(s) will be shared among the parties.

Invention: Any new and useful process, machine, manufacture, or composition of matter, or any useful improvement thereof. In general, an invention may be defined as anything that is made, designed, or created by people and therefore not naturally occurring. General types of inventions include processes (e.g., methods), machines, articles of manufacture, and compositions of matter (such as synthetic molecules and mixtures of compounds).

Inventor: Under U.S. law, a person who makes an intellectual contribution to one or more issued claims in a US patent. Therefore, anyone who made even a shared contribution to one claim of a patent is an inventor. Thus, inventorship of a patent application may change as the patent claims are changed during prosecution of the application. Inventorship is a legal issue and may require an intricate legal determination by a patent professional. Inventorship is not the same as authorship on an academic paper. For example: (i) funding a project (or being everyone's boss) does not confer inventorship; (ii) suggesting a problem to solve does not confer inventorship, but actually solving the problem does; (iii) acting totally under someone's direction does not confer inventorship; and (iv) performing a test on a composition or device without modifying the composition or device does not confer inventorship to the composition or device. Throughout this guide unless specifically described otherwise, the term inventor includes individuals listed on a patent or patent application as well as creators and contributors who have shared in creating the value of intellectual property that might not be patented. The Intellectual Property Disclosure Form asks for all contributors to be named and TTBD makes the determination regarding who is an inventor for patenting purposes based on the law. However, in this guide the term inventor shall refer to all creators and contributors.

Know-How: Something a person knows how to do better than anyone else. For example, a process such as a drug screening method, animal model, or manufacturing method may be published and/or otherwise well known in the art, but the fact that a specific research group has that method up and running, while for another party it may take months to years to get set up with no guarantee of success, means that the specific research group has "know-how" that the other party does not. Know-how may be secret or not.

License Agreement: This is a contract between the holder of an IP right (the licensor) and another party who wishes to obtain the ability to use that right (the licensee). A license agreement grants rights from the licensor in a defined technology to the licensee for a period of years and is often limited to a particular field of use and/or region of the world. The defined technology may be patent rights, copyrights, tangible materials or other forms of IP. A license agreement is used with both startup companies and with established companies. A license agreement may be non-exclusive (the licensor can license the same rights to multiple licensees) or exclusive (the licensor agrees not to license the same rights to any other licensee).

Licensee: Any outside third party who has been granted a license to certain technology and who has capabilities to further utilize and/or develop the technology.

Material Transfer Agreement (MTA): A legally binding agreement between two or more parties that describes the rights of the party providing certain tangible materials and the responsibilities and restrictions on the use of such materials by the receiving party. Materials provided under a MTA are most commonly biological samples, research models, compounds, and, sometimes, software (although a non-commercial license is more commonly used for software). Generally an MTA addresses a one-way transfer of materials to a recipient and does not include exchange of money or compensation for research.

Net Royalty Income: The royalty funds remaining from Royalty Income after OHSU deducts any out-of-pocket expenses for development of such IP (which includes but is not limited to repayment of the direct expenses paid by OHSU for patent, copyright, and/or trademark protection).

Non-Confidential Summary (NCS): A short summary that describes a technology in a non-confidential manner without describing the actual technology in detail. The NCS contains a brief summary of the technology, the problem the technology is addressing, a synopsis of the market for the technology, names of the inventors, IP protection status, and any relevant publications that may describe the technology further.

Non-Disclosure Agreement (NDA): A legal contract between two or more parties that outlines confidential material, knowledge, or information that the parties (one or both) wish to share with one another for certain purposes, but wish to restrict access to or by third parties. NDA is synonymous with CDA.

Option Agreement: An agreement between two parties that provides one of the parties with the right, but not the obligation, to license a specific IP asset on terms agreed upon some time in the future. An option agreement is sometimes used to enable a third party to evaluate a technology for a limited time period in order to inform their licensing decision.

Patent: An IP right granted to an inventor to exclude others from making, using, offering for sale, or selling the invention or importing the invention for a limited time period. Therefore, a patent provides the patent holder with the exclusive right to exclude others from practicing the invention claimed in the patent.

Patent Cooperation Treaty (PCT) Application: An international patent law treaty, concluded in 1970, that provides a unified procedure for filing patent applications in each of its contracting states. A patent application filed under the PCT is called an international application, or PCT application. A PCT application does not itself result in the grant of a patent, since there is no such thing as an international patent. A PCT application, which establishes a filing date in all contracting states, must be followed up with entering into national or regional phases in order to proceed toward grant of one or more patents.

Person Having Ordinary Skill In The Art: Often referred to as a person of ordinary skill in the art, the skilled addressee, person skilled in the art, or simply the skilled person, is a legal fiction found in may patent laws throughout the world. This fictional person is considered to have the normal skills and knowledge in a particular technical field, without being a genius.

Principal Investigator (PI): The lead scientist for a particular well-defined research project, such as a laboratory study or clinical trial. The PI is also the person who takes direct responsibility for completion of a research project, directing the research, and reporting the results.

Prior Art: Constitutes all information that has been made available to the public in any form before a given date that might be relevant to a patent's claims of originality. The definition of a prior art reference is very broad. Any published patent, patent application, technical journal article, catalog entry or marketing description, poster at a research conference, abstract from a research conference, slide or document posted on the Internet, and (depending on the country) presentations open to the public may all serve as references. A prior art reference need not be from a peer-reviewed or even published article (a poster or draft posted on the Internet is sufficient). A patent application may be used as a reference even when the claims are not allowed and/or the application was later abandoned.

Provisional Application: A patent application that establishes an early filing date, but that is never examined and therefore does not directly mature into an issued patent. A Provisional Application is never published and therefore never becomes part of the public domain.

Public Disclosure: Any release or sharing of information with anyone who is not an OHSU employee. This includes seminars or other talks given on OHSU campus where scientific liaisons or other non-OHSU employees are present.

Royalty Income: Money or other valuable consideration received in exchange for the transfer of OHSU IP and reimbursement of out-of-pocket expenses for IP protection, marketing and licensing.

Request for Continued Examination (RCE): A re-filing of the same patent application that starts the patent prosecution process over again.

Research Collaboration Agreement (RCA): A framework for how a collaboration or partnership is to proceed between two or more parties, what each party is responsible for under the SOW, how materials and data are to be shared, what the publication rights of each party may be, and other aspects including how new IP that may arise from the SOW will be managed.

Research Services Agreement (RSA): A contract through which an industry partner funds an industry-initiated research project at OHSU. These projects often involve the testing or evaluation of the sponsoring industry's proprietary new therapy, compound, diagnostic or device in a preclinical model.

Royalty Sharing Agreement: An agreement between the inventors of a particular invention that clearly delineates how the inventors' share of the Net Royalty Income will be shared.

Scope of Work (SOW): Describes the specific aims and activities that will be conducted by one or more parties for a particular project, as well as outlines the milestones, deliverables, and timeline for such project.

Secondary Factor of Non-Obviousness: Types of evidence required in a patent application that are contrary to a finding of obviousness of the invention. Examples of evidence of secondary factors include evidence that the prior art actually teaches away from the invention – more preferably that the prior art cited against the application by the examiner teaches away from the invention. Other examples of secondary factors include evidence that others have tried and failed to make the invention, evidence that there is a long felt need for the invention in the art (provided by references around the time of the patent filing), evidence that others disbelieved that the invention could be made, and evidence of the commercial success of the invention. Still other evidence of secondary factors includes a showing that the invention produces unexpected results that were not predicted by the prior art. Similarly, evidence that the making of the invention involved overcoming technical hurdles that were unforeseen by the prior art may also be important in overcoming an obviousness rejection.

Sponsored Research Agreement (SRA): A contract through which an industry partner funds a research project for OHSU-initiated research projects. These projects must be consistent with and support the academic, research and/or healthcare mission of OHSU.

Startup: A new company that is dependent on the licensing of OHSU-owned IP for its formation.

Tangible Materials: Any asset that is physical in nature and can be touched. Examples of tangible materials at OHSU include research reagents, cell lines, transgenic mice, software programs, plasmids, and antibodies.

Technology: As used in this guide, the term technology is synonymous with invention.

Term Sheet: A bullet-point document outlining the basic financial terms and commercial development milestones of a license agreement.

Trade Secret: Any information maintained as confidential by an entity. May include a process for manufacturing a product, or an unpublished discovery or result. Alternatively, it may include employment information, sales information, or any other non-public information about the organization.

Trademark: A brand name and includes any word, name, symbol, device, or any combination, used or intended to be used to identify and distinguish the goods/services of one seller or provider from those of others, and to indicate the source of the goods/services.

UNIT: OHSU UNITs comprise School of Medicine, School of Nursing, School of Dentistry, Research Development and Administration, Central Services, and Hospital.

ACRONYMS

AO:	Agreements Officer	**PCT:**	Patent Cooperation Treaty
BD:	Business Development	**PI:**	Principal Investigator
CDA:	Confidentiality Disclosure Agreement	**RCA:**	Research Collaboration Agreement
CIP:	Continuation-in-Part	**RCE:**	Request for Continued Examination
EARs:	Export Administration Regulations	**RSA:**	Research Service Agreement
FRE:	Fundamental Research Exclusion	**SAG:**	Startup Advisory Group
IAA:	Inter-Institutional Agreement	**SOW:**	Scope of Work
IP:	Intellectual Property	**SPA:**	Sponsored Projects Administration
ITARs:	International Traffic in Arms Regulations	**SRA:**	Sponsored Research Agreement
MTA:	Material Transfer Agreement	**TDM:**	Technology Development Manager
NCS:	Non-Confidential Summary	**TTBD:**	Technology Transfer & Business Development
NDA:	Non-Disclosure Agreement	**U.S.:**	United States of America

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