

# Hidden Technology Transfer

*Elizabeth Hart-Wells, PhD*

---

*Elizabeth Hart-Wells, PhD, is assistant vice president and director, Office of Technology Commercialization, at Purdue Research Foundation in West Lafayette, Indiana.*

---

Technology transfer occurs via myriad vehicles, not all of which are immediately apparent. Put differently, technology transfer is not solely effected via a traditional license agreement developed by an office of technology transfer (OTT). It is the goal of this chapter to present contemporary examples of technology transfer that occur at most academic research institutes but often outside of the OTT's purview. By understanding the different mechanisms and how and when they are used, the mechanisms can become tools used by the OTT to increase technology commercialization.

Put differently, it is insufficient to assume the OTT possesses the unfettered ability to commercialize any technology disclosed to it. The OTT must understand the various legal provisions within research contracts, material transfer agreements, and clinical trial agreements that can masquerade under nonassuming titles. Not doing so can and does lead to overlapping obligations to third parties, which then can open the institute up to untoward legal liabilities. It is likely that in your institute, more than one office or department is responsible for the vehicles by which technology can and is transferred. Working with the responsible entities can be a good place to start weaving a coordinated institutewide support network for technology transfer. Before you reach out to your colleagues in the office of sponsored programs, let's review some basics in hidden technology transfer using provisions extracted from actual agreements.

First, let us establish and agree that the transfer of technology, in its most generic definition, requires having legal rights in or to an intangible asset (e.g., intellectual property). Further, this chapter assumes the institute is the owner of those legal rights in and to the subject intellectual property. It is also assumed that an infrastructure exists at the institute that develops and manages each of the applicable instruments referred to in this chapter. A note of caution when reading the exemplary provisions provided below—in practice, intellectual property provisions should be taken in the context of an entire

contract. Specifically, the scope of definitions for salient terms (such as invention, data, results, and personnel) must be understood to evaluate fully the impact of any hidden technology transfer.

## License Agreements

The OTT is often tasked with the exclusive responsibility to negotiate agreements in which the institute grants a license to one or more existing assets. Therefore, the OTT has direct control over the terms and conditions of such grant of rights. This level of transparency to the OTT (e.g., all of the obligations in the license agreement are known to the OTT) is the baseline from which the transparency to the OTT of the obligations made in the other instruments should be compared and sought.

## Material Transfer Agreement (MTA)

The MTA has become the bane of the nearly every stakeholder's existence, with good reason—they are predictably unpredictable in scope, breadth, and depth. Currently, the degree to which rights to resultant assets transferred under an MTA can range from none, such as the uniform biological material transfer agreement (UBMTA)<sup>1</sup> to exclusive licenses to full assignment of rights to prospective intellectual property. It is essential that the OTT know about and understand the implications of these agreements before setting forth to implement a commercialization strategy for a resultant asset.

Provisions found in MTAs that impact an OTT's ability to commercialize a resultant asset come in different shapes and sizes. Examples are given that exemplify concepts the adroit OTT should establish either exist or do not prior to taking on commercialization of intellectual property (IP).

### Example 1: Prospective Assignment/License and Continuing Commitment of Resources

*All Inventions that are developed during the course of the Research and that either solely relate to improvements, modifications, or new uses of the Material, or that are directly related to or directly derived from the Material, (for example, antibodies, tissue or cells, cell lines, genes, proteins, diagnostics, assays, new therapeutic indications, information concerning the crystal struc-*

**Hidden Technology Transfer***Elizabeth Hart-Wells, PhD*

*ture of the Material, and new methods of manufacture and administration of therapeutics developed from Investigator's or Recipient's use of the Material) will be solely owned by Provider ("Provider Inventions").*

*To the extent that Recipient and/or Investigator are statutorily prohibited from assigning the Provider Inventions to Provider, Recipient and/or Investigator hereby grant to Provider an exclusive, worldwide, royalty-free license, with the right to grant sublicenses, to make, use, sell, have made, have sold, offer for sale, and import all Provider Inventions and otherwise exploit all IP rights therein, subject only to the rights of the U.S. Government in federally-funded Inventions.*

*Upon Provider's request and at Provider's expense, Recipient and/or Investigator shall take such actions as Provider deems necessary or appropriate to obtain patent or other proprietary protection in Provider's name with respect to any of the Provider Inventions.*

In this example from an MTA, the institution is left with not only no (commercialization) rights to resultant assets, but also an obligation to provide cooperative services to the provider. The former (e.g., exclusive licensing prospectively) can and does occur. The reasons often cited for accepting this position is the institute has placed a higher benefit on the performance of research than the protection of an asset, which, incidentally, cannot be created absent the original material.

The latter (e.g., provision of services) can be straightforward or can be tricky. While giving the provider assurance it will receive cooperation in protecting provider inventions, this particular provision is without clear metes and bounds on what actions the provider can require the institute to take.

For example, this obligation is devoid of a reasonableness standard. Does this provision also require doing what the provider deems appropriate in enforcing the IP? Is it limited to executing formal documents required by national laws in obtaining patent protection?

What is your institution's policy on cooperating with a third party under such circumstances, e.g., research undertaken that was aided by an MTA? Most institutions have difficulty staffing sufficient effort to protect its own IP and would not be keen on being legally required to subsidize protection of another party's IP. Ideally, the OTT and the office responsible for MTAs know and embrace the same policies.

### Example 2: Freedom-to-Operate License

*For any invention or discovery (including without limitation a Modification) created or first reduced to practice as a result of Recipient's use of the Material that would itself be infringed by the practicing of Provider's patent rights in or to the Material, Recipient grants Provider a non-exclusive, royalty-free, sub-licensable license for all purposes. Provider agrees to notify Recipient after grant of any such sub-license to a third party.*

An automatic grant of a license of this nature may be employed when the provider of the material has associated patent rights and is capping any liability that it may be exposed to as a result of the recipient using the original material. The goal of this license is to permit the provider freedom to operate using its own material. Because it is rarely the goal of an academic research institute to usurp development of another's assets, this license is often granted to avoid inadvertent development of IP that does just that. This type of license grant is not aimed at permitting the provider to develop the recipient's resultant inventions per se.

Therefore, the institution remains in a position to commercialize the resultant asset, subject to the right granted to the provider under this provision. Such a license grant could be requested by any entity sharing proprietary materials, including public or nonprofit organizations such as research institutes. In the case in which the research institute is the provider, the license customarily reads (in lieu of the underlined text) "for research and education purposes."

Another mechanism by which an MTA can change the disposition of resultant assets is if the material is used in a project or an experiment not specifically permitted under the MTA.

### Example 3: Consequences of Unauthorized Use

*If Recipient breaches this obligation, then Recipient agrees that any intellectual property rights or other legal rights in any work product developed or discovered in the course of such prohibited research shall be automatically assigned to Provider notwithstanding any other provision of this Agreement.*

The contract provision of example 3 addresses consequences of use of the material outside the agreed-upon scope of research. This provision is often embodied in MTAs and is nearly always rendered moot by the investigator's compliance with the limitations on the use of the material. Nonetheless, the transfer of rights to resultant assets from the institution to the provider make it relevant. If only to rule out its applicability, the OTT should determine if such a legal obligation applies to a disclosed invention at the outset of disclosure. To do so, simply ask the investigator working under the MTA about the full use of the material.

## Sponsored Research Agreements

Research is one certain path to innovation, and research requires resources. The vehicles employed by research institutes to transfer the needed resources to drive innovation address commercialization of any resultant IP. The resources are often financial but can also include equipment, data sets, a visiting scientist, etc. In order to chart an informed commercialization strategy for any invention, an effective OTT official should be well-versed in its institute's policies on acceptable contract provisions regarding the disposition of IP in all manner of research agreements.

Because a lack of standardization exists across the full spectrum of research agreements, the impact of the provisions on technology transfer vary. Two key varying factors are the type of sponsor (e.g., nonprofit, government agency, for-profit) and/or the facts surrounding the research itself (i.e., investigator-initiated, translational, fee for service, etc.). This section is organized to highlight provisions common under a specific set of circumstances that affect the commercialization of an institution's IP.

## Federal Funding Agency

To the extent use of the word *hidden* in the title of this chapter implies *secret* or *covert*, this section should dispel that connotation. There is little secret about the technology commercialization intentions of the U.S. government. United States law and regulations applicable to IP funded in whole or in part by the U.S. government includes without limitation 35 U.S.C. §200 et seq., 15 U.S.C. §3710a, and 37 C.F.R. Part 401. This statute is referred to affectionately by the technology transfer community as the Bayh-Dole Act. By virtue of the existence of the OTT, your institute has erected the infrastructure to implement and comply with the obligations under the Bayh-Dole Act. Nonetheless, a complete and comprehensive command of the Bayh-Dole Act is essential in the training of any and all OTT officials.

With respect to inventions resulting from a project supported by federal funding, the Bayh-Dole Act governs the disposition of the rights to that invention. However, from time to time, a federal agency may amend certain provisions (or implementing guidelines) to support specific programmatic goals. One such program can be found at the National Cancer Institute (NCI). This program requires recipient institutes to accept the following obligation before the creation of any subject inventions.

### Example 4: Nontraditional License Associated with a Federal Grant

*Institution agrees to grant to Provider: (i) a paid-up, nonexclusive, non-transferable, royalty-free, world-wide license to all Recipient Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, or co-exclusive if applicable, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Recipient Inventions on terms to be negotiated in good faith by Provider and Recipient.*

*Provider shall notify Recipient, in writing, of its interest in obtaining an exclusive license to any Recipient Invention within six (6) months of Provider's receipt of notice of such Recipient Invention(s). In the event Provider fails to so notify Recipient, or elects not obtain an exclusive license, then Provider's option shall expire with respect to such Recipient Invention, and Recipient will be free to dispose of its interest in such Recipient Invention in accordance*

*with Recipient's policies. If Recipient and Provider fail to reach agreement within ninety (90) days, (or such additional period as Provider and Recipient may agree) on terms for an exclusive license for a particular Recipient Invention, then for a period of six (6) months thereafter Recipient shall not offer to license the Recipient Invention to any third party on materially better terms than those last offered to Provider without first offering such terms to Provider, in which case Provider shall have a period of thirty (30) days in which to accept or reject the offer.*

Note, the provider is not the U.S. government or NCI, but rather a third party with whom the NCI has a formal agreement. Because, in this case, the success of the NCI program relies on access to proprietary materials obtained from for-profit entities, NCI procured those materials, and in doing so, reasoned the value of further immediate research with these materials justified the deviations in the IP from the standard arrangements with grant recipients. This value proposition is not unlike the decision-making process institutes use on a case-by-case basis to transfer its own proprietary materials (see the "Material Transfer Agreement" section). In fact, this provision offers the OTT an example of an alternative arrangement that may be useful for its own purposes.

The provision can be dissected into the following parts: (i) perpetual license for research purposes, (ii) first option to exclusively license for all purposes or first option to co-exclusively license for all purposes, (iii) two-way reporting, and (iv) a six-month right of first refusal. One or some combination of these parts may be useful in breaking in impasse in a negotiation with a licensee that also wishes to support research of the licensed invention.

### **Private, Nonprofit, and Charitable Organizations (Foundations)**

Foundations are nonprofit organizations that exist to support efforts to educate, advocate and impact the course of a specific interest, such as a disease, a policy, or a convention. To achieve its mission, a foundation may sponsor research that offers a potential solution or generates evidence to answer an unanswered question or generally advances the state of affairs for its specific interest. While the foundations that sponsor basic research are often not in the business of technology commercialization per se, intellectual property created with foundation funding often must be used in a manner to support the foundation's mission.

To this end, foundations approach the business development of IP in an altruistic manner guided chiefly by ensuring all who so desire have ready access to the resultant assets, which include intellectual property, data, and results. Types of commercialization requirements that may be incorporated into such research agreements include, assuming the institute has an IP policy:

- *Reporting requirements:* (i) of any applicable disclosure of an invention, (ii) of published manuscripts and abstracts, (iii) of commercialization activity including execution (and copies thereof) of applicable licenses, (iv) of patent protection activities, and (v) of any decision to discontinue commercialization activities.
- *Revenue sharing:* At a level that may be (i) a precisely established revenue-sharing structure (i.e., 10 percent of revenue), (ii) established at the time of invention based on the relative contributions of other parties involved in the making of the invention, (iii) established at the time of first sale based on the relative amount of total research and development dollars invested, and/or (iii) some precise percent (i.e., 200 percent) of the amount of the applicable grant.
- *Assignment:* Foundations may require assignment of the resultant asset if (i) any invention that results from the sponsored research, (ii) the recipient institute discontinues support of subject intellectual property, or (iii) the recipient institute materially breaches certain obligations with respect to commercialization of a resultant asset.
- *Commitment to commercialization:* The recipient institute represents that any business arrangements established directed to resultant assets will support and enable the mission of the sponsoring foundation.
- *Compulsory licensing:* A mandate for the recipient institute to license to a particular party or under a particular set of circumstances may be issued in the research agreement. Any evaluation by the OTT of an invention subject to compulsory licensing should consider the potential impact of such provisions on securing a licensee.
- *Grant of license:* An automatic grant of license to the sponsoring foundation to enjoy for use to support its mission. In this case as in the above, any commercialization strategy developed by the OTT for a resultant asset should consider the potential impact of reserving rights for the sponsoring foundation.

## For-Profit Organizations (Corporate)

The interest of a for-profit entity funding research at an academic institute of higher learning is wholly in juxtaposition to the interest of an academic investigator performing research. As a consequence, these research agreements present an arsenal of technology transfer opportunities but solely to that of the sponsoring for-profit entity. The effective OTT official can learn from these tactics but at a minimum needs to fully appreciate their relevance to any invention he or she may be attempting to commercialize.

Here, it is useful to segregate by the type of research proposed. For example, one type may be investigator-initiated in which an investigator submits a proposal to the for-profit with the intent of obtaining funding to carry out the proposed work (Example 5). Another type may be of the translational research ilk. In this case, the for-profit may have contacted the investigator and wishes for he or she to validate its own test product (Example 6). Yet, in another case, an investigator and a representative of a for-profit have synergistic interest and wish to collaborate to explore in related but unexplored waters (Example 7).

One can imagine that in each of these fact patterns, the nature of any agreement memorializing the different relationships would also, in turn, tackle IP differently.

### *Investigator-Initiated Research Funded by a Corporation*

The commercialization of intellectual property arising under Example 5 should support the performance and continuance of the research project, which was the original idea of the investigator. However, absent resources to perform the work, the idea remains intangible in its purest form. Therefore, research agreements often offer the for-profit sponsor an option to license any resultant IP. If the option is directed to obtaining an exclusive license, then an automatic grant of a nonexclusive license to the for-profit for research and development purposes, which survives expiry of the option, may also be granted (similar to the approach used in Example 4). One example of contract language embodying a business arrangement under Example 5 is provided.

### **Example 5. Corporate Funded Investigator-Initiated Research**

1. *INSTITUTE shall have sole and exclusive ownership rights to all Inventions and all Results arising out of the Research, subject only to Sponsor's option rights under this Agreement.*

2. *INSTITUTE shall notify Sponsor, promptly and in writing, of any Invention which is disclosed to INSTITUTE. Sponsor shall treat as confidential and not disclose to any third party the contents of any notice provided to it by INSTITUTE, and shall not use any such information for any purpose other than to exercise its rights under this Agreement.*
- 2.1 *In consideration for the funding provided by Sponsor under this Agreement, INSTITUTE grants to Sponsor, and Sponsor accepts from INSTITUTE, with respect to each Invention, an option to negotiate a non-exclusive or exclusive license under Patent Rights claiming that Invention to develop, make, have made, use, market, offer for sale, sell, and import products in the field of \_\_\_\_\_ (an "Option"); provided, however, that Sponsor's rights to the Option shall be subject to Federal Patent Policy [OPTIONAL: and the rights of a third party which collaborates on or sponsors the research at INSTITUTE which results in the Invention]; and provided further that INSTITUTE may refuse to agree to grant an exclusive license if the relevant Invention relates to a research tool (as described in NIH Principles and Guidelines with Respect to Sharing Biomedical Trial Resources). Sponsor may only exercise the Option if: (a) there are no uncured defaults or breaches of this Agreement or any other agreement between Sponsor and INSTITUTE at the time of exercise of the Option; (b) Sponsor timely exercises the Option in writing; [OPTIONAL: and (c) Sponsor pays Patent Expenses in accordance with this Agreement].*
3. *If Sponsor elects to exercise an Option, it must do so by written notice to INSTITUTE during the period commencing upon the date on which Sponsor receives INSTITUTE's notice of that Invention and ending sixty (60) days thereafter (the "Option Term"). If Sponsor duly exercises the Option, INSTITUTE and Sponsor shall negotiate in good faith the terms of a master license agreement during the period commencing upon the date on which INSTITUTE receives the notice and ending ninety (90) days thereafter (or such longer period as the parties may mutually agree) (the "Negotiation Period").*

### *Translational Research Funded by a Corporation*

In Example 6, the for-profit entity is providing one or more existing assets to the investigator as well as financial resources. It is unlikely a rational-minded businessperson would do so, if in doing so, the business would be exposed to uncapped legal or business liability. Because research institutes are often bastions of unique and specialized expertise, a for-profit may find it cost effective to pay the institute to perform certain development work. Often, the opportunity to be first to publish on a new product, among other things, incentivizes the investigator to participate in this nature of collaboration. Moreover, the for-profit obtains the benefit of the acclaimed reputation of the investigator and/or institute for either product validation, product improvement, or both. The validation or product development opportunity offered under this scenario is reflected in research agreements drawn to such scenarios.

To do that effectively, the research agreement typically sets clear boundaries between existing assets and those created under the research agreement. The latter is usually transferred exclusively (either by assignment or by grant of an exclusive license) to the for-profit sponsor, which may include inventions as well as know-how, results, materials, etc. Alternatively, rights in and to an asset created under such research agreement may be designated as jointly owned between the parties. Another alternative business structure can include a two-pronged approach: (i) for-profit ownership of the resultant assets that arise under a specific set of circumstances (e.g., those that would be deemed to have been enabled by the sponsor's business) and (ii) institute ownership of assets that fall outside those defined. An example of the latter follows.

#### **Example 6: Translational Research**

*The Parties agree that any Invention made or developed by INSTITUTE or the Principal Investigator, investigator or any employee, agent or independent contractor of INSTITUTE during the term of this Agreement which arises directly from the Sponsor's Confidential Information disclosed to INSTITUTE pursuant to this Agreement, or which use or modify (i) materials provided to INSTITUTE or the Principal Investigator by Sponsor or (ii) data emanating from the direct performance of the work in accordance with Appendix A shall be*

*owned solely by Sponsor (“Sponsor’s Inventions”). INSTITUTE and the Principal Investigator hereby assign to Sponsor all right, title and interest in and to all Sponsor’s Inventions and shall cooperate in the filing and prosecution of patent applications and take all necessary or appropriate actions to assist the Sponsor in obtaining patent or other proprietary protection for Sponsor’s Inventions. In particular INSTITUTE and the Principal Investigator shall not publish Sponsor’s Invention or parts of it till the Sponsor will have applied for an industrial property right. Sponsor shall reimburse INSTITUTE for any reasonable expenses incurred at Sponsor’s request to secure title or legal protection for any Sponsor’s Invention.*

In most cases of an institute making an assignment of rights to intellectual property, a grant-back license to the institute for research and education is made. Such a grant is often required under applicable institute policies, as it enables the institute to meet its goals and mission. Although these grant-back licenses can be very straightforward, an example of a detailed grant-back provision follows.

#### Example 8: Grant-Back License to Institute

*Sponsor grants to INSTITUTE a non-exclusive, royalty-free, irrevocable license to all data, results and IP for research, scholarly use, teaching, education, patient care incidental to the foregoing (“Non-Commercial Uses”) and the right to sublicense to a government agency; nonprofit university or other educational institution; organization of the type described in §501(c)(3) of the Internal Revenue Code; scientific or educational organization qualified under a state nonprofit organization statute; or a foreign equivalent of the foregoing (each a “Non-Commercial Organization”) solely for Non-Commercial Uses.*

#### Collaborative Research with a Corporation

In the scenario of Example 7, the OTT has a responsibility to understand if not participate in the discussions establishing a collaborative agreement that is a win-win for all involved. By this, it is meant, each party is poised to meet its overarching mission and specific goals

of the collaboration. To do this effectively, each party must articulate its goals at the outset of any negotiation. The OTT, particularly if it is not directly responsible for negotiating such collaborative research agreements, should use this early intervention as an opportunity to inform the goals of collaboration on behalf of its institute. The commercialization infrastructure should reflect the collaborative nature of the relationship. For example, either joint ownership or cross-licensing of resultant intellectual property, data, and/or results can be one approach to achieve equity with respect to IP.

Because the reality is that interests change over time, the collaborative research agreement should contemplate what happens to commercialization efforts, whether under way or not, at discontinuance by either party. In Example 6, the institute would not be in a strong position to pursue commercialization efforts on its own (even via licensing of its own IP) if the for-profit discontinued support. However, in Example 7, either party could plausibly be in a position to continue the project with a different research partner. This is yet another opportunity for the OTT to inform the institute's business decisions.

## Services Agreements

The last vehicle addressed is the services agreement. The research suitable for a services agreement is different from the scenario of Example 7 in that often the institute's participation is limited to carrying out a standard methodology, with little to no analysis applied, and using the specialized know-how of the investigator. The performance of such service is unlikely to yield a publication or be used to support a basic research grant for a specific research program because the for-profit may provide little context to understand the impact of any data. For example, the for-profit may provide only unidentified samples thereby limiting any analysis to the discreet data generated and to the formation of causative or correlative results. These types of services are often provided by institutes having a dedicated lab (often called a core) that carries out these standard services and can even be associated with standard rates or a fee schedule. In this case, any resultant intellectual property is likely assigned to the sponsor of the services. A straightforward example of the IP provision from a service agreement follows.

### Example 9. Fee-for-Service/Development for a Corporation

*Any information, invention or discovery, innovation, suggestion, idea, communication and report (whether patentable or not) (collectively "Invention"),*

*conceived, first reduced to practice, made or developed by INSTITUTE or the Principal Investigator in the course of performing the scope of work described in Appendix \_\_, other than Sponsor's Inventions (as defined below), shall be owned by Sponsor.*

The OTT may wish to establish an inventory of the investigators and/or the core services at its institute that perform work under service agreements with any frequency. Aside from helping evaluate disclosed technologies, this information could give the OTT a comprehensive landscape of its institute's offerings to support more collaboration and in turn aid marketing efforts externally.

## Conclusion

It is hoped that the information in this chapter will provide a basis to put the OTT commercialization activities in a broader context of the research institutes' policies on technology transfer. Understanding what vehicles transfer technology and how, can help the effective OTT official prevent inadvertent transfer and expand his or her negotiation tools. Conversely, if policies have not been articulated sufficiently to address technology transfer in the context of grants, contracts, or sponsored programs, then a dialogue needs to occur among the responsible parties, including the OTT and leadership within the institute. Having a uniform position on the value of intellectual property assets by all offices involved, not just the OTT, is important for the success of an institute's entire IP enterprise.

## Acknowledgments

Thank you to Dana Murray, Esq., of the University of Maryland, Baltimore, for her guidance, collegiality, and editorial prowess.

## Notes

1. The uniform biological material transfer agreement can be found at [www.nhlbi.nih.gov/resources/tt/docs/ubmta.pdf](http://www.nhlbi.nih.gov/resources/tt/docs/ubmta.pdf).