

FACULTY GUIDE TO COMMERCIALIZATION ▶

Baylor
College of
Medicine

TABLE OF CONTENTS

COMMERCIALIZATION FUNCTIONAL TEAMS . . 3

REASONS TO ENGAGE IN COMMERCIALIZATION 3

COMMERCIALIZATION GOALS AT BAYLOR . . 4

BCM COMMERCIALIZATION LEADERSHIP . . . 5

BAYLOR LICENSING GROUP (BLG) MEMBERS . . 6

BAYLOR LICENSING GROUP RESPONSIBILITIES. 8

- Academic Goals and Industry Goals. 8
- Type of Agreements That Govern Academic-Industry Interactions. 10
 - License Agreements 10
 - Sponsored Research Agreements (SRAs) . . 10
 - Material Transfer Agreements (MTAs) 11
 - Data Transfer Agreements (DTAs or DUAs) . 12
 - Research Collaboration Agreements 12
 - Confidential Disclosure Agreements (CDAs or NDAs) 12

RECOMMENDATIONS FOR BCM FACULTY CONSIDERING AN INDUSTRY CONSULTING RELATIONSHIP. 14

DISCLOSURE SUBMISSION & MANAGEMENT . . . 17

- Ownership of Intellectual Property: The BCM Patent Policy 17
- What, How, and When to Disclose 18
- Disclosure Management: Invention Disclosure Analysis. 18

TYPICAL COMMERCIALIZATION CONSIDERATIONS & STRATEGIES FOR DIFFERENT TYPES OF INVENTIONS. 20

- Therapeutic methods & new uses for existing compounds 20
- Therapeutic compounds or molecules. 21
- Drug targets 21
- Diagnostic test/biomarkers 22
- Medical devices. 22
- Research tools. 22
- Software/smart phone applications 23

MARKETING 23

- BLG Marketing Efforts 23
- PI Marketing Efforts 24

LICENSING 25

- Term Sheet Elements. 25
- Preparation of License Agreement & Negotiation of Agreement 26
- Legal Review of License Agreements. 27
- Type of License Agreements 27
 - Exclusive License Agreements. 27
 - Non-Exclusive License Agreements 28
- Inter-Institutional Agreements (IIAs) 28
- Distribution of License Agreement Revenue . . 29
- Post-License Agreement Management 30

PATENT STRATEGY. 31

- Patent Decision Making Process 31
- Patentable Subject Matter 32
- Requirements for Patentability 32
 - Novelty 32
 - Non-obviousness 32
 - Utility. 33
 - Sufficient written description. 33
- Inventorship on a Patent. 33
- The Patent Prosecution Process 34
 - Use of Outside Patent Counsel 34
 - Provisional Patent Applications. 35
 - Non-Provisional Patent Applications 35
 - The National Phase Entry Decision. 35
 - The Patent Examination Process. 36
 - Restriction Requirements & Office Actions. . 36
- The America Invents Act ("AIA") and Patenting Practices at Baylor. 37

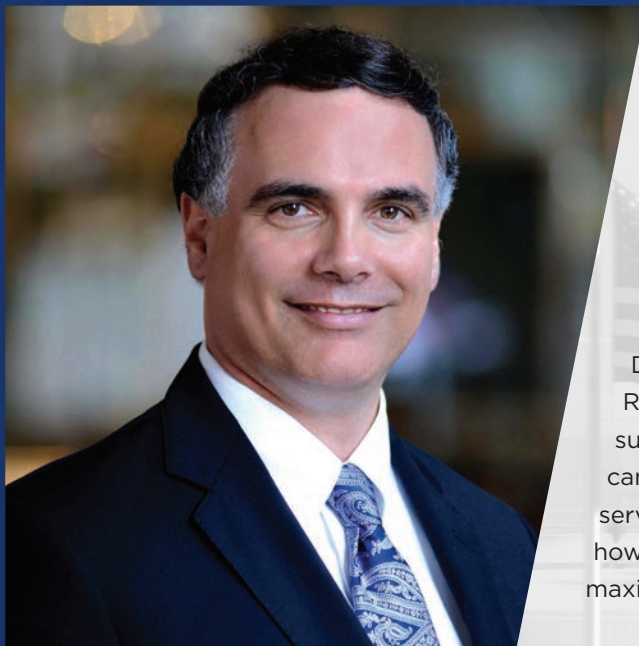
INNOVATION DEVELOPMENT: BAYLOR COLLEGE OF MEDICINE INNOVATION DEVELOPMENT CENTER (IDC) 38

- IDC Asset Development Model 38
- Asset Identification, Selection, Validation, Maturation & Commercialization. 38-42
- Sources of Asset Investment Capital 42
 - IDC Pilot Project Awards Program 42
 - NIH SBIR/STTR Program. 42
 - State Commercialization Grant Programs. . 43
- Company Ownership. 44
- College Support of Newly Formed Small Businesses 45
- Responsibilities & Expectations of the Faculty Founder 45
- Partnering Initiatives: Building Relationships . 46

CONCLUDING REMARKS 46

CONTACT INFORMATION 47

INTRODUCTION: DR. ADAM KUSPA



Welcome to the Faculty Guide to Commercialization at Baylor College of Medicine. This guide provides tools and resources designed to demystify the process of commercialization. BCM has three teams that are actively working together in an integrated way to catalyze commercialization of the college's research assets: (i) the Baylor Licensing Group (BLG), (ii) the BCM Innovation Development Center (IDC), and (iii) BCM Technologies, Inc. These teams play distinct, yet interdependent roles and each contributes essential components needed for commercial success. Additionally, the Dan L. Duncan Institute for Clinical & Translational Research (ICTR) contributes important resources to support clinical translation of many of our promising candidate technologies. This guide will explain the services offered by each team and demonstrate how you as a faculty member can work with them to maximize the impact of your research program.

If you have questions about the licensing process, or questions about whether a discovery in your lab might be patentable, or if you're interested in pursuing commercialization grant funding, this guide can help you find answers. The members of BLG, IDC, and BCMT are here to serve the faculty community at BCM, and I encourage you to take advantage of the expertise of each group. They look forward to answering your questions and to working with you.

Baylor College of Medicine is committed to expanding its commercialization activities so that the college's cutting-edge research programs can be leveraged to develop new products and services that benefit patients, form the basis for new business enterprises, and provide opportunities for new jobs in high-growth sectors. BCM's increasing focus on commercialization complements ongoing efforts by the Texas Medical Center and its member institutions to build critical mass in the biomedical commercialization community in Houston. These activities fit hand-in-glove with the college's growing research engine to yield new and exciting possibilities for commercial success.

Baylor College of Medicine

FACULTY GUIDE

TO COMMERCIALIZATION AT

BAYLOR COLLEGE OF MEDICINE

The purpose of this Guide to Commercialization is to provide a resource that describes key elements of the commercialization process and to provide a description of the teams and individuals involved in this process so that members of the BCM research community can understand who does what, why they do it, and how they can serve you.

There are three functional teams that work closely together to implement an integrated, coordinated approach to technology commercialization at Baylor College of Medicine. The college's commercialization teams are led by Adam Kuspa, Sr. VP for Research. These functional teams are:

- **BAYLOR LICENSING GROUP (BLG):** BLG is the team that is responsible for licensing and managing the college's intellectual property assets. **BLG is "the agreements team"** – they are responsible for negotiating many different agreements with industry partners, including license agreements, sponsored research agreements, material transfer agreements, and other agreements. Additionally, BLG coordinates patent filing and prosecution activities around the college's IP assets.
- **BAYLOR COLLEGE OF MEDICINE INNOVATION DEVELOPMENT CENTER (IDC):** IDC is the organizational unit that is responsible for managing the college's efforts around technology asset development and business development activities. **IDC is the "asset development team"** – they administer and coordinate activities related to investment in a select group of BCM's most promising technology assets. IDC supports efforts to pursue commercialization grant funding, and coordinates visits with pharmaceutical, biotech, and device companies who are interested in BCM research programs.
- **BCM TECHNOLOGIES, INC. (BCMT):** BCMT is BCM's wholly-owned for-profit venture development subsidiary corporation. **BCMT is the "start-up company team"** – they provide services around company formation and strategy, including securing company management and seeking investment opportunities for companies in their portfolio. BCMT coordinates the innovative "podco" program at the college, whereby companies are formed and operated in a very capital efficient manner to determine if there is a sustainable business opportunity.

The overall mission of BCM's commercialization teams is two-fold: (i) **to maximize the impact of the research enterprise** at Baylor College of Medicine by supporting the development and commercialization of the college's intellectual property assets into products and services that benefit the public, and (ii) to **foster the development of a culture of entrepreneurship** where commercialization is viewed as a natural extension of the college's research activities.

Why would a member of the BCM research community wish to engage in commercialization? What are the benefits of commercialization to BCM and its research community?

- **Maximize the impact of research:** As a leading biomedical research institution with globally recognized excellence across many research disciplines, **BCM should be strongly impacting the next generation of therapeutics, devices, diagnostics, and other solutions that can impact patient's lives.** These benefits won't happen without commercialization. Relationships with commercial partners will open doors that will ultimately enhance the prestige and reach of the college's formidable research enterprise.
- **Public benefit and fulfillment of our institutional mission:** As a member of the BCM research community, participation in commercialization **opens the door for your discoveries to be developed into products and services that benefit society.** This activity fulfills public expectations around funding of research – as well as the BCM mission to create and apply science and discoveries to further education, healthcare, and community service locally and globally.
- **Partnering with industry:** Working with industry may **bring new collaborators and new perspectives to your research program.** This activity may open doors for you to tap into new resources that may impact your research in different ways.
- **Starting a company:** Commercialization may provide **opportunities to be involved in the formation, operationalization, and funding of a new business entity.** Only a small subset of technologies merit start-up company formation as the route to commercialization, and the decision to form a start-up company is normally based on the prospect that start-up can secure a sustainable competitive advantage.

- **Revenue generation:** Successful license agreements can provide a ***source of unrestricted revenue that the college can use to support its research mission***; and this revenue provides ***direct benefits to the BCM researchers*** who developed the commercialized technology.
 - **Opportunities for funding:** Partnering with a commercial entity may ***provide a source of funding to support commercialization-focused research*** through industry-sponsored research or programs like the SBIR/STTR program, CPRIT commercialization grants, or funding from non-profit foundations that are interested in specific disease areas and commercial approaches to treat them.
 - **Opportunities for student education & growth:** Commercialization activities provide ***opportunities for students and trainees to learn about various aspects of the commercialization process*** by serving as interns with the Baylor Licensing Group, Innovation Development Center, and through potential employment/consulting relationships with start-up companies.
- What are we trying to accomplish? Goals for technology commercialization at BCM:**
- ***To catalyze a culture of entrepreneurship*** by providing opportunities to inform, educate, and support the BCM research community's efforts to engage in commercialization.
 - ***To produce significant growth in commercialization activities and outcomes*** by improving processes and systems for soliciting and managing invention disclosures, and effectively negotiating mutually beneficial agreements with industry partners.
 - ***To grow industry sponsored research at BCM*** by promoting key BCM research programs and faculty to industry and coordinating meetings between faculty and industry representatives to build relationship that lead to collaborations.
 - ***To accelerate and support the development & maturation of novel therapeutics and devices*** based on discoveries from BCM laboratories by providing support for critical proof-of-concept research and mapping the route to clinical translation for our most promising biomedical assets.
 - **How will we know if we're succeeding? Metrics of success:**
 - Growth in license agreement deal flow.
 - Growth in invention disclosure submissions.
 - Growth in executed biomedical asset validation/maturation projects.
 - Growth in start-up company formation + achievement of development and funding milestones.
 - Growth in IND filings associated with BCM's biomedical assets.
 - Growth in patent filings and issued patents associated with BCM's biomedical assets.



BCM COMMERCIALIZATION TEAMS

LEADERSHIP



ADAM KUSPA, PH.D.

Sr. Vice President, Research

As leader of the college's research activities and enterprise, Dr. Kuspa is charged with overseeing and coordinating all innovation development and commercialization activities at BCM. Dr. Kuspa's leadership

has been instrumental in the development of the integrated multifunctional team approach to commercialization at BCM.



MICHAEL DILLING, PH.D.

Director, Baylor Licensing Group

Michael directs the activities of the team that is responsible for managing and licensing Baylor's intellectual property assets. Director of the Baylor Licensing Group since 2011, Michael has 14 years of technology licensing experience at BCM. Dr. Dilling

has a Ph.D. in Genetics from Texas A&M University and an MBA from the University of Memphis. Dilling states: "I love being able to lead a team that directly helps BCM faculty commercialize their research discoveries and navigate often complex relationships with industry. I am fortunate to get to lead a very skilled team that is focused on getting results for the college. Each new agreement we sign opens a door for a BCM biomedical innovation to enter the commercial sector."



ANDREW WOOTEN, M.S., M.T.M.

Executive Director, Baylor College of Medicine Innovation Development Center

Andrew is leading efforts to develop BCM's top innovation concepts into mature biomedical assets that are ready for commercialization. This involves

acquisition of required resources and expertise as well as the creation of programs and infrastructure at BCM. It often involves the creation of new development companies to help focus these resources and expertise. Andrew has 24 years of entrepreneurial and business development experience in the biotechnology industry. He has been personally involved as an employee/founder of three university startup ventures. He has worked in business development with two large biotechnology companies and with one mid-market private equity firm. Finally, Andrew has managed university technology commercialization and research park operations. In this capacity he has helped to launch over 25 new ventures. Andrew has an M.S. in Biotechnology from the University of Georgia and an M.T.M. in Finance from Mercer University.



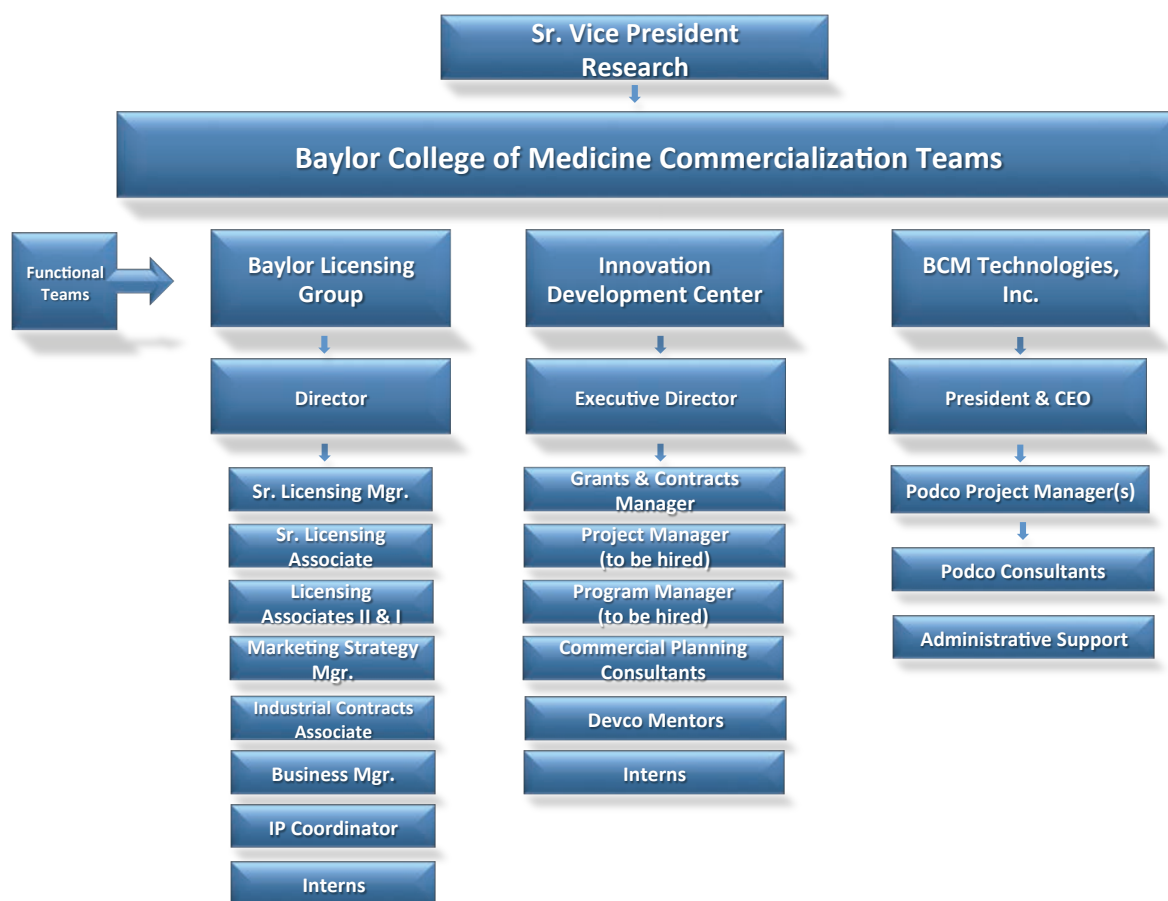
CAROLINE POPPER, M.D.

President, BCM Technologies, Inc.

Dr. Popper directs the activities of BCM Technologies, BCM's wholly-owned for-profit venture development subsidiary. BCMT is responsible for managing and administering start-up company formation for new ventures formed around the college's

biomedical assets. Dr. Popper has been President of BCM Technologies since 2007, and she also leads the activities of Popper & Company, a biomedical industry consulting firm. Dr. Popper has more than 21 years of hands-on biotech/life sciences operating experience. An internist and pathologist, she combines medical and scientific perspective with knowledge gained from managing a wide spectrum of life sciences businesses in diagnostics, devices and drug discovery. Dr. Popper has an M.D. from the University of Witwatersrand (South Africa) and her M.P.H. from Johns Hopkins University.

BCM Commercialization Teams Organizational Chart



BAYLOR LICENSING GROUP (BLG) MEMBERS

LISA BEVERIDGE

Sr. Licensing Manager

Lisa joined the Baylor Licensing Group in 2001. She brought with her more than 25 years of experience in the medical field including clinical, sales, technical support, marketing, market research and business development in various medical companies. She has negotiated nearly 150 license/option and interinstitutional agreements for BCM. Prior to joining BCM, Lisa negotiated the rights for multiple technologies and therapeutics from other pharmaceutical companies, biotechnology companies and academic institutions for Aventis Pharma (previously Rhone Poulenc Rorer) in order to benefit therapeutic development in its Gencell division.

TERESE RAKOW, PH.D.

Sr. Licensing Associate

Terese joined the Baylor Licensing Group in 1999. She has negotiated nearly 140 licenses, options and interinstitutional agreements for BCM. These licenses, to both established and startup companies,

include diagnostics, therapeutics, drug discovery platform systems, research tools and reagents. One gene therapy vector is in Phase IIb trials in an ex vivo therapeutic regimen for one application and under review for others. In addition, Terese has been responsible for negotiating in-licenses for platform technologies in the diagnostic field and disease specific diagnostics. Other agreements include early access/beta test agreements and service agreements for diagnostic services. Terese received a Ph.D. in Zoology and Genetics from Iowa State University.

BRIAN PHILLIPS, PH.D.

Licensing Associate II

Brian joined the Baylor Licensing Group in May 2012. He earned his Ph.D. in Biomedical Sciences with the Genes & Development Graduate Program at the University of Texas M.D. Anderson Cancer Center and his B.S. in Biology from the University of Houston where he graduated cum laude and as a member of the Honor's College. Prior to joining Baylor College of Medicine, Brian spent five years

working as a Licensing Associate at Rice University's Office of Technology Transfer and then at The Texas A&M University System's Office of Technology Commercialization, where he led commercialization activities in the biomedical, agricultural, and chemical engineering markets. During this time, Brian helped execute over thirty license agreements worth more than \$1.5M in upfront fees and spin-out seven startup companies

MERCY S. CHEN, PH.D.

Licensing Associate I

Mercy joined the Baylor Licensing Group in 2011. Previously, Mercy held a position as a contracts associate in the Office of Sponsored Programs at Baylor College of Medicine and was in charge of reviewing and negotiating a variety of research related contracts with industry as well as other non-profit organizations. Mercy received a B.S. in Biochemistry from the University of California, Los Angeles, and a Ph.D. in Molecular and Cellular Biology from Baylor College of Medicine. As part of her graduate studies, Mercy was awarded a Department of Defense predoctoral fellowship to study the self-renewal and survival of cancer stem cells, with a focus on the WNT/bCatenin pathway in breast cancer stem cell survival.

Q. ANDY GUO, PH.D.

Marketing & Licensing Specialist

Andy joined the Baylor Licensing Group in 2013. As our marketing strategist, he has been very proactive in reaching out to our potential industry partners and marketing innovative technologies developed at BCM. Andy received a Ph.D. in Translational Biology & Molecular Medicine from Baylor College of Medicine. Prior to joining BLG, Andy conducted translational neuroscience research in BCM's Huffington Center on Aging and had a solid record of scientific publications in high impact journals. He has also had more than three years of clinical rotation and research experience in the Department of Neurology at Baylor College of Medicine and at the Memory Disorders and Dementia Clinic of the UT Physicians Neurocognitive Center.

KIMBERLY WEIDERHOLD, PH.D.

Industrial Contract Associate

Kim joined the Baylor Licensing Group in 2014, after having previously worked as a Contracts Associate for the Office of Sponsored Programs. Kim's transition to the Baylor Licensing Group resulted from a plan to integrate the responsibility for managing industry agreements into one team to improve processes and reduce confusion for faculty and our industry partners. Dr. Weiderhold received her Ph.D. in Cell & Molecular Biology from Baylor College of Medicine in 2012. Kim conducted research in the lab of BCM PI Li-yuan Yu-Lee to elucidate how phosphorylation of the NudC protein by the mitotic kinase Aurora B regulates cytokinesis, which has implications for developing strategies to regulate tumor cell division.

NELLIE VILLARREAL

Business Manager

Nellie's Baylor Licensing Group responsibilities include database management for disclosures, license agreements, collection and disbursement of license income, licensee compliance, and general administrative office duties. Nellie has been with Baylor College of Medicine since 1998, working in a variety of administrative positions in Ophthalmology and the Office of Faculty Affairs. Joining BLG in January 2003, Nellie has extensive experience in database management, SAP accounting systems and customer service.

VERONICA HINOJOSA

Intellectual Property Coordinator

Veronica assists BLG team members with administrative matters associated with intellectual property prosecution and maintenance. She serves to coordinate communication with outside legal counsel, inputs legal correspondence into the BLG database, and she manages compliance issues associated with federally-funded grants. Veronica joined Baylor College of Medicine in 2013, and she has held past positions as a legal assistant.

BAYLOR LICENSING GROUP

RESPONSIBILITIES OF THE BAYLOR LICENSING GROUP

WHEN ACADEMIA MET INDUSTRY: The members of the Baylor Licensing Group work at the intersection of two very different cultures. Successfully negotiating agreements with industry partners requires a pragmatic approach for flexibility, equity, and balance in the final agreement.

- **Key academic concerns that govern our approach to industry relationships.**

Dissemination of information – right to publish.

The academic world revolves around the generation and dissemination of information. Publication and presentation are the lifeblood of academic faculty members. We always strive to preserve the right to publish research results resulting from work done as part of collaboration with an industry partner. Because this work may be of a proprietary nature, the industry partner may require time to review a pending manuscript before it is submitted for publication to insure that it does not contain confidential information owned by the industry partner or to allow time for the preparation and filing of a patent application, if necessary.

Commitment of the partner to develop the technology and move it forward:

Diligence milestones: Our goal as an academic institution is to license our discoveries to commercial partners who will actively commit resources to develop these technologies into products and services. To ensure that this is done, we typically negotiate diligence targets and milestones in to our agreements (for example, licensee shall file an IND within three years of the agreement date). These diligence milestones are always subject to negotiation, and our objective is to be sure that the company is using good-faith efforts to move the technology forward along the path to commercial development.

Non-practicing entities: As a matter of practice, we don't license BCM-owned intellectual property to non-practicing entities (NPEs). NPEs are organizations/companies that aggregate patents in particular technology sectors without actually practicing the underlying intellectual

property (commonly referred to as “patent trolls”). They approach companies active in technology sectors where they hold patent portfolios and propose to license their portfolios to these companies. Refusal by the targeted company may be met with legal action for infringement by the NPE.

Equitable management of intellectual property rights:

Preservation of the PI's ability to conduct research program:

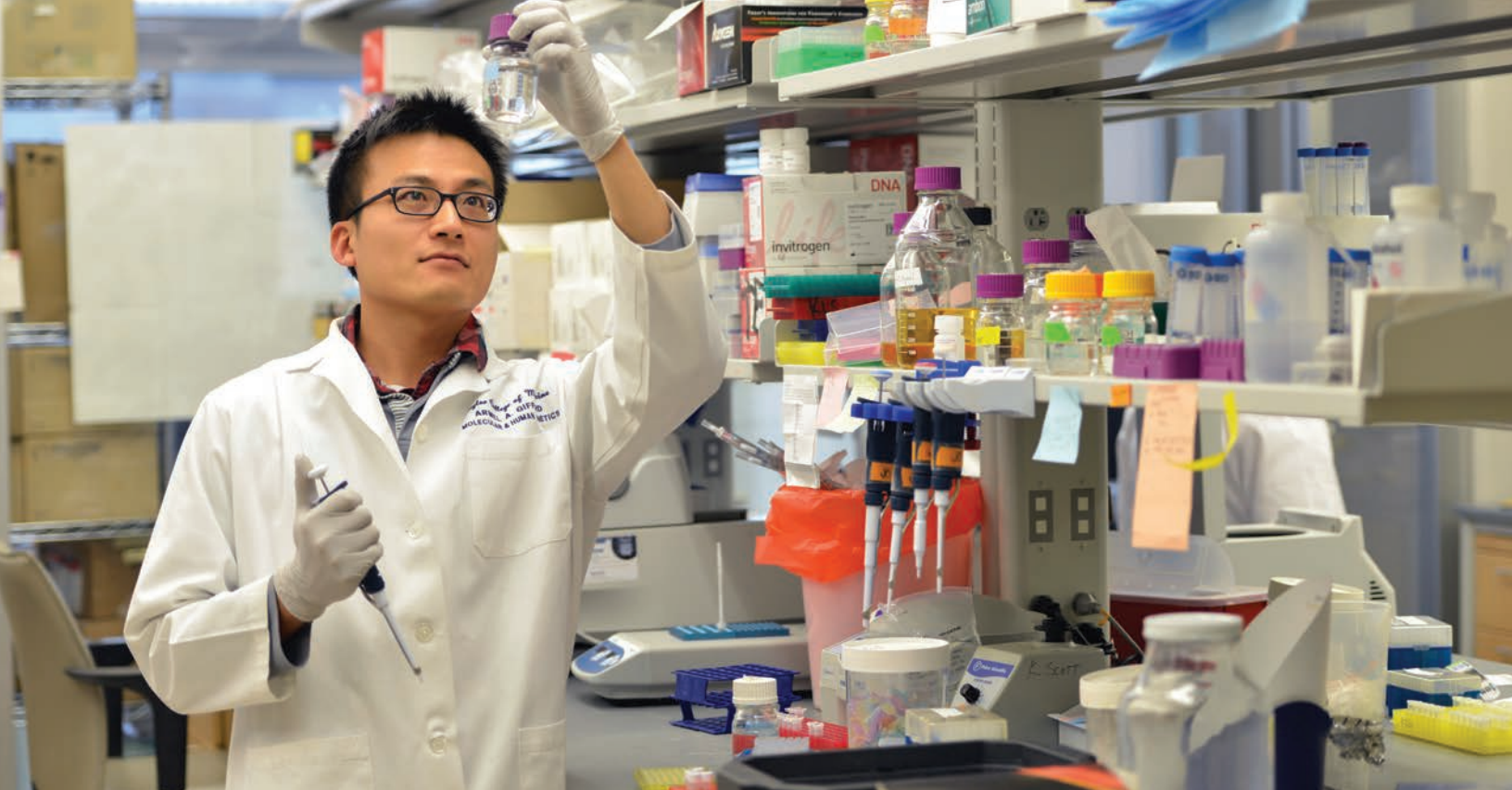
It is of paramount importance that agreements with commercial partners don't impede the ability of PIs to conduct non-commercial research in the academic setting. Depending on the nature of the agreement and the relationship, it may be necessary to agree not to conduct research of a commercial nature with the licensed technology, but we will always preserve the right to engage in non-commercial academic research.

Equitable sharing in commercial success.

In an agreement with a commercial partner, the financial benefit to the inventors and institution should be proportional to the level of our contribution to product or service. In just about every case, the industry partner will generally assume vast majority of development risk and should be expected to reap the majority of the reward. Most technologies that we license to industry partners are many years away from achieving clinical entry, regulatory approval, or marketing approval.

- **Key industry concerns that govern their approach to academic relationships.**

Preserving proprietary information: While the academic world focuses on the dissemination of information, industry is often focused on the protection and preservation of proprietary information that they wish to shield from their competitors. These alternative views on the management of information mean that compromise is necessary when academics and industry work together. We as academics have to respect industry's desire to protect proprietary information, and they have to be willing to accommodate our need to publish research results and disseminate information. Both sides have to give a little to make the relationship work.



Freedom to operate: Industry partners will often avoid agreeing to terms in collaborative agreements with academic institutions that may negatively impact the industry partner's ability to use their technology, or to use something new that an academic PI develops using an industry technology. The industry partner doesn't want to share technology with an academic PI, only to have the PI invent something new with it that the industry partner is blocked from using in the absence of a license from the academic partner. From the academic perspective, however, if our PI develops something that adds value to a technology, we'd like to capture some of that value for the benefit of the institution and the PI.

Risk management & mitigation: When a company licenses an early-stage technology from an academic institution, they are taking on a considerable risk. Depending on the nature of the technology, it can take a decade or more from the date that a license agreement is signed until the licensee receives approval from the FDA or other regulatory agency to begin marketing the product. For this reason, companies seek to limit their exposure to risk by negotiating license fee structures that are "back-end loaded," meaning that fees during the early stages of the licensing relationship will be modest, and will escalate as the technology is developed and de-risked. This contrasts from the academic perspective such that we desire to reap value during the early phase of the

licensing relationship to protect against the prospect that the technology may never make it to market as a licensed product.

Focus on the bottom line: Companies are in business to make money by selling products and services and to deliver value to their shareholders. Decisions made by a commercial partner are often (almost always) driven by a healthy degree of concern for the impact of a project on the bottom line. When a commercial partner seeks a collaboration or licensing relationship with an academic institution, they are focused on the value that the collaboration or license stands to deliver to the company.

Reaching Agreement: The fine art of compromise. Each agreement between BCM and a commercial partner is a product of a unique negotiation. Our philosophy is to engage in principle-based, pragmatic negotiation that results in a balanced, mutually acceptable agreement that meets the needs of both parties. Unbalanced agreements that unacceptably favor one party over the other never work out well in the long run. ***Neither party should expect to get everything it wants from the negotiation, but both parties should expect to get certain items that they need to make the transaction worthwhile. Reasonable people get things done!***

■ **Overview of the Types of Agreements that Govern Academic-Industry Interactions (TABLE 1)**

License Agreements: License agreements confer a package of rights to the commercial partner to allow them to use BCM-owned technology in the commercial marketplace to develop products and services based on the BCM-owned intellectual property asset. Focal points of the negotiation of a license agreement revolve around the financial terms of the agreement and obligations of the commercial licensee to commit resources to the development of the licensed technology. Depending on the level of exclusivity, license agreements may be divided into three categories.

- **Exclusive license agreements:** Exclusive license agreements involve a license of rights to a single company. These agreements are generally associated with patented therapeutic and device technologies that must go through clinical trials and regulatory approval processes before they can be sold. Exclusivity is necessary to justify the licensee's investment to develop the technology and carry it through the regulatory approval process.
- **Semi-exclusive license agreements:** Are typically granted to a limited number of companies (often three) and frequently involve licenses of research tool technologies (antibodies) to for-profit distributors of research tool reagents to the scientific community. This agreement format is infrequently used.
- **Non-exclusive license agreements:** As the name implies, technologies that are licensed on a non-exclusive basis are often licensed to multiple companies. Non-exclusive licenses are generally associated with non-patented research tool technologies (knockout mice, cell lines engineered to have certain characteristics, expression vectors, etc.). Companies will readily license these technologies if they are priced appropriately because they save the company the time and expense associated with independently developing the tool.

Sponsored Research Agreements (SRAs):

SRAs define the terms and conditions for a collaborative research project between an industry sponsor and a BCM PI. They are driven by industry needs to work with an academic PI who possesses specific expertise of interest to the industry partner (typically expertise that the company can't readily obtain in-house). Key elements of SRAs include:

- **Project work scope and budget:** This section will define the experiments that are to be conducted in the academic PI's laboratory, and the associated costs (including overhead) of doing the work. BCM's current overhead rates can be found at the following link: http://intranet.bcm.edu/?tmp=/research/or/proposals/nihapp/bcm_indirect_costs
- **Schedule for payments and deliverables:** Research conducted under an SRA is often funded in stages, with an up-front payment at the initiation of the work, and additional payments due as the work progresses and interim report deliverables are met.
- **Publication rights:** As an academic institution, we must preserve the ability of our PIs to publish research results arising from industry-sponsored research. However, the company that funded the work has a vested interest in it as well, and will typically demand a period to review any pending publication before it is submitted for review by a journal. The sponsor will typically be entitled to an additional delay if they desire that a patent application should be filed pertaining to the results described in the manuscript. It is important for the BCM PI to understand their obligations associated with the supplying a manuscript to the industry sponsor prior to submitting it for review, and that they understand the potential length of delays that the sponsor may be entitled to request.
- **Intellectual property rights:** Industry sponsors are frequently interested in acquiring rights to any intellectual property that arises from the sponsored research project. We adopt the stance that ownership of any intellectual property emerging from a sponsored research project rests with the party that developed it, and can be jointly owned if both parties contributed to the development of the IP. Typical sponsored research agreements will provide the industry sponsor with a time-limited option to negotiate terms for an exclusive license to any BCM-owned IP that emerges from the work. Industry sponsors may often be granted a non-exclusive license to use any project IP for their own internal research purposes. In many cases, this non-exclusive license is all the sponsor really wants and they may decline the option to negotiate an exclusive license.

Industry sponsors will sometimes insist that they should be granted ownership to intellectual property that emerges from the research project, and will provide the rationale that since they are paying for the research,

they should own the outcome of the work and they don't want to be placed in a situation of having to "pay twice" by taking a license to intellectual property resulting from the collaboration. However, granting ownership to intellectual property emerging from a sponsored research project is inappropriate and wrong because college faculty members are not employees of the industry sponsor and the sponsor is not entitled to own their intellectual work product, and because the industry sponsor is not paying for the true and total cost of the work. In most cases, an industry sponsor is seeking to leverage a faculty member's research program that has been in development for years and has been funded by government and/or non-profit foundation grants. In most cases, mutually satisfactory resolution to intellectual property related matters in SRAs can be found if both sides have a sufficient will and incentive to reach agreement.

Material Transfer Agreements (MTAs): MTAs define the terms and conditions for the use of research materials when they are transferred from one institution to another. They are the documents that everyone "loves to hate." PIs don't like MTAs because they regard them as an administrative burden and impediment to the progress of their research. On the BLG front, we negotiate and execute over 1,000 MTAs annually, and this process consumes considerable time and resources on our end. But, ***because research materials are often proprietary and have value, MTAs are necessary.*** MTAs govern the following principles:

- **Ownership:** The provider of the material maintains ownership of the material.
- **Third party transfers:** The recipient should not engage in further transfer of the materials to other third parties without the knowledge or consent of the provider.
- **Commercial use:** The recipient cannot use the materials for commercial purposes without the consent of, or in the absence of, an additional agreement with the provider that governs commercial use.
- **Derivatives and modifications:** In most situations the recipient of the material retains ownership to modifications or derivative materials, but the original provider retains ownership of their original material that is incorporated in the derivative.
- **Properties associated with the material:** Transferred materials are experimental in nature and the recipient is responsible for their use of the material.

The vast majority of MTAs govern academic-to-academic transfers of research materials, and are fundamentally simple agreements that require minimal, if any, negotiation to execute and complete. They are typically executed very quickly. Academic MTAs typically do not allow the use of the transferred research material in human subjects. BCM is a signatory to the Uniform Biological Materials Transfer Agreement (UBMTA), a template agreement that simplifies and facilitates the MTA process when both institutions use this agreement format. We are actively exploring ways to streamline the MTA process to make it more efficient and less time-consuming for all parties. The burden imposed by MTAs is not at all unique to Baylor, and there is recognition across the academic community that better ways of executing and managing MTAs need to be found. BLG will be a part of that solution.

If clinical use of the transferred material is contemplated, additional terms may be required revolving around indemnification of the institution supplying the material and assurances that the institution using the material for clinical purposes will use it in accordance with the appropriate regulatory oversight (IRB approval, etc.). MTAs for materials that will be used clinically can take longer to execute because they are more complex agreements and the management of liability and risk is of paramount importance to both institutions. The standard UBMTA template does not contemplate or allow clinical use of the transferred material. Therefore, a separate MTA agreement format (or perhaps another agreement format entirely) is required if the transferred material will be used in human clinical studies.

When a BCM PI is providing materials to another institution, it is important to wait until the MTA is executed before sending the materials to your colleague.

- **MTAs involving the transfer of materials from a for-profit company to a BCM PI:** Agreements governing the transfer of materials owned by a for-profit company to a BCM PI often involve more extensive negotiation, and the negotiations are typically focused around two key issues:
 - **Intellectual property rights to derivatives or modifications of the supplied material:** As a condition for allowing an academic PI access to materials that it owns, a for-profit company may insist upon rights up to and including outright ownership to any new

materials or intellectual property that are made with or incorporate the transferred material. The company's motivation for doing this is partially rooted in freedom-to-operate concerns, but it may also open doors for the company to capture value generated in the academic PI's laboratory. This practice can impact intellectual property and materials developed through research conducted years after the date of the original transfer. Our view is that the scope of these provisions is often over-reaching and we focus on negotiating more equitable terms, however, the company that owns the material may choose to deny access to it unless the recipient agrees to the terms offered.

It is critically important that the PI understands and appreciates the implications of any IP-related "strings attached" to research materials received from industry under an MTA. We strongly recommend that the PI carefully weigh the pros and cons and consider the impacts of unfavorable MTA terms to their research programs. If there are viable alternatives for obtaining a needed material under more favorable terms (we realize this isn't always the case), then those alternatives should be explored.

- **Publication rights involving publications generated with the use of the transferred material:** The owner of the material may attempt to place restrictions on our ability to publish results obtained with the transferred material. As an academic institution, we must preserve the right for our PIs to publish the results of their research, and it is unacceptable for BCM to allow a third party to potentially block our ability to publish or require their permission in order for us to do so. Not only is it unacceptable as a matter of principle for BCM to be obligated to seek permission to publish, acceptance of such a restriction could put us in conflict with the Fundamental Research Exclusion provisions of U.S. export control restrictions.
- **Negotiation timespan:** Negotiation of MTA terms with a for-profit supplier of research material can be time-consuming, but this is because we are working to protect the interests of the institution and the PI. For-profit owners of materials are often reluctant to significantly change the terms of their MTAs because they own their

material and they wish to dictate the terms under which they are willing to allow third party access to it. We have examples of MTAs that have impacted (and continue to impact) research at BCM over a decade after the original document was signed. The effects of these agreements can be very far-reaching.

Efforts to streamline MTA processing and management will probably have minimal impact on MTAs involving the transfer of materials from a for-profit company to BCM. Corporate MTAs vary widely in their terms (they're drafted by corporate legal counsel), and unless the pharma/biotech industry could agree upon a standardized MTA template governing transfers to academia, there is no opportunity to automate or streamline management of this type of MTA. For the foreseeable future, industry-to-academia MTAs will require hands-on negotiation.

Data Transfer/Use Agreements (DTAs/

DUAs): DUAs are analogous to MTAs, and they define the terms and conditions for the use of information contained in data sets. These agreements are becoming more frequent **and they're principally used to manage the use of data** that involves patient health information, in particular individually-identifiable health information that is protected under HIPAA regulations. DUAs are often associated with data sets involving clinical information collected from multiple institutions and used by multiple institutions. Both institutions involved in the transaction are seeking assurance that the data will be collected and used in accordance with the appropriate regulations for the protection of patient health information.

Research Collaboration Agreements: These agreements define the terms and conditions for research collaborations under which each party contributes their own funding and materials to the collaborative research project. The agreement will define the parameters of the research project, along with the roles, responsibilities and deliverables for each party. The agreement will also spell out the management of publications and intellectual property resulting from the collaboration.

Confidential Disclosure Agreements (CDAs or NDAs): Two parties will enter into a CDA when they desire to exchange confidential,

proprietary information and they wish to protect it against inappropriate disclosure. In BCM's case, companies will often elect to sign a CDA after they have reviewed any available non-confidential information associated with a technology, and now wish to conduct a more in-depth review of proprietary information in order to determine if they wish to enter in to a licensing or sponsored research relationship. CDAs typically deal with the following key issues:

- CDAs define the scope of proprietary information that will be shared between two parties, and the time period during which it must be kept confidential (typically 5 yrs., but can vary).
- CDAs define the purpose for which the shared proprietary information can be used, and

this purpose is normally to allow the parties to evaluate whether they wish to enter into a further business relationship. Execution of a CDA does not bind either party to enter in to a business relationship, nor do they typically convey any license rights to allow the company to use the information for commercial purposes.

- CDAs can be unilateral, meaning that the direction of information transfer is one-way (from the college to the company), or they can be bilateral (or mutual) such that both parties will share their confidential or proprietary information with the other party.
- **Important note:** BCM faculty members are not authorized to sign CDAs that bind the institution or information owned by it.

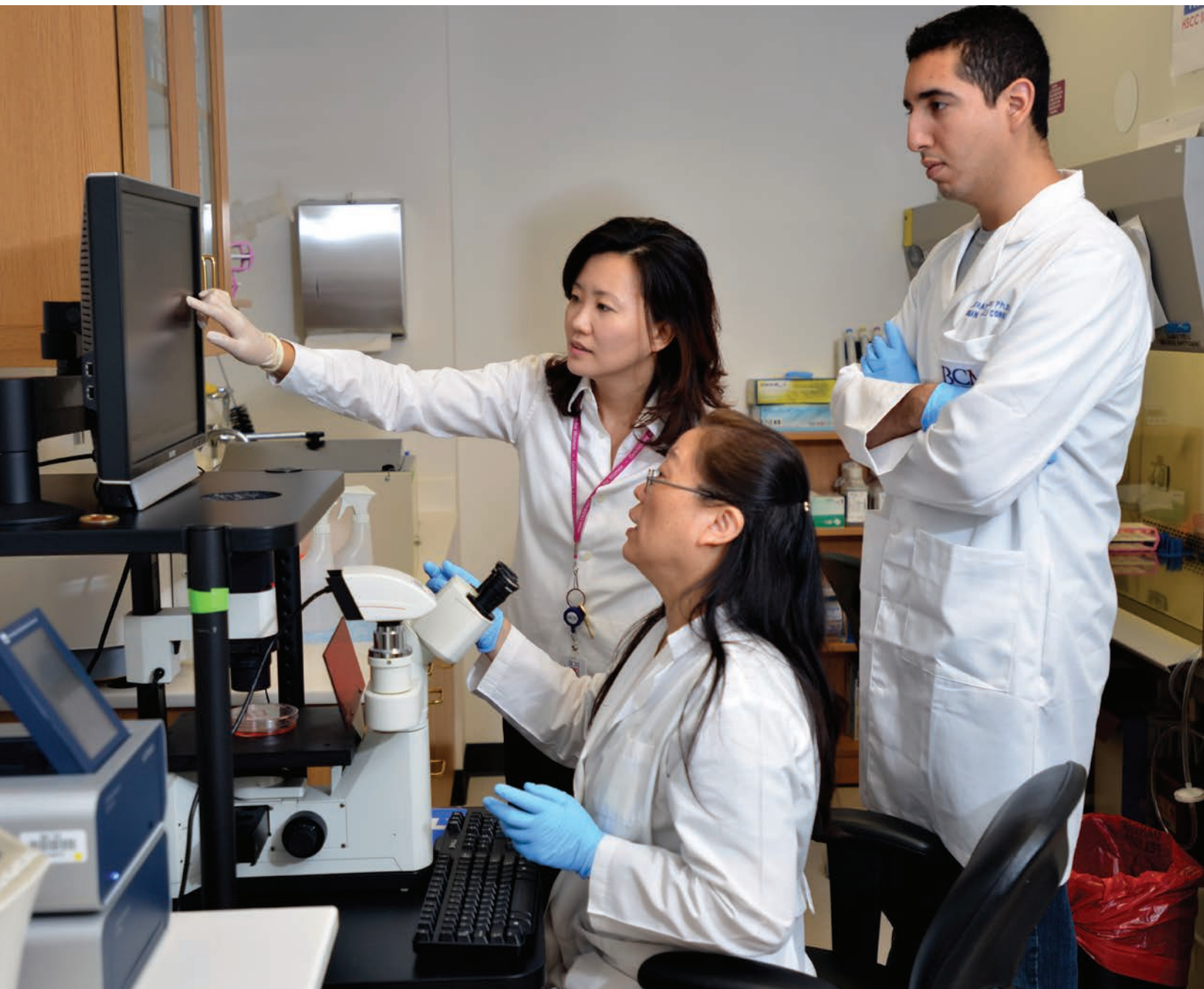


TABLE 1: Different types of agreements and responsible parties at BCM

Responsible Party	Agreement Type
Baylor Licensing Group	Exclusive or Non-Exclusive License Agreements. Material Transfer Agreements (MTA) – nonclinical, basic science. Sponsored Research Agreement (SRA) – nonclinical, basic science. Data Use Agreement (DUA) or Data Transfer Agreement (DTA). Research Collaboration Agreement – nonclinical, basic science. Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) associated with licensing activities or non-clinical agreements.
Institute for Clinical & Translational Research (ICTR)	Clinical Trial Agreement (CTA) – industry sponsored. Clinical Services Agreement (CSA) or Clinical Supply Agreement – industry sponsored. Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) associated with industry-sponsored clinical agreements.
Sponsored Programs Office (SPO) – Office of Research	Clinical Trial Agreement (CTA) – federal or non-profit foundation funding. Clinical Services Agreement (CSA) or Clinical Supply Agreement – federal or non-profit foundation funded. Grant subawards and subcontracts. Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) associated with federal or non-profit foundation funded clinical agreements.
Other Agreements/Responsible Parties	Consulting Agreements – Faculty member and their legal counsel; subject to reporting requirements to BCM Compliance and Audit Services. Fee-for-service Agreement – Office of General Counsel Testing Agreement – General of Counsel Software In-Licenses/Equipment Loan Agreements – BCM Supply Chain Mgmt.

■ **Recommendations for BCM Faculty Members Considering an Industry Consulting Relationship**

Baylor College of Medicine PIs are thought and opinion leaders in their chosen fields of study, and for-profit companies frequently desire to access our faculty members' expertise. As a part of that process, the company may wish to enter in to a consulting relationship with a faculty member. BCM allows its faculty members to consult with industry with the understanding that any such consulting activity should be consistent with the college's mission of applying science and discoveries to further education, healthcare and community service locally and globally. College policy around the management of outside consulting activities is evolving, and these activities will be managed by the BCM Department of Corporate Compliance and Audit Services. Faculty members should read and understand their obligations under the

Disclosure of Outside Interest policy as stated on the Compliance and Audit Services intranet site (<http://intranet.bcm.edu/index.cfm?tmp=/compliance-audit/home>).

Faculty members contemplating a consulting relationship with a for-profit company should consider and be mindful of the following issues:

- **Conflict of commitment:** BCM permits its faculty members to engage in consulting activities to no more than twenty percent (20%) of their total effort. Faculty members must report any consulting activities to the Conflict of Interest Office.
- **Conflict with a faculty member's academic research program:** Faculty members should exercise care that any consulting relationship they are contemplating will not lead to conflict with their academic research

program, particularly with regard to any third party agreements related to funding of the laboratory's research program.

- **Parties to the agreement:** A consulting agreement is an agreement between you and the company for whom you will provide consulting services. Baylor College of Medicine is not a party to such an agreement, and as such the college does not sign these agreements. Members of the Baylor Licensing Group will provide general advice to faculty entering consulting relationships with industry, however, this advice is ***not legal advice, nor is it advice rendered on behalf of the college***, and it should not be interpreted as such.

- **Legal representation:** The company with whom you will consult will be advised by its own legal team (which solely represents the interests of the company, and not yours). We very strongly recommend that as a faculty member, ***you should obtain legal advice from your own personal attorney to guide you through the consulting agreement process***. Any attorney that you select to represent your interests should have considerable experience with drafting and negotiation of consulting agreements.

- **Important elements in consulting agreements:**

- **General statement:** As you begin the consulting agreement negotiation process, the company may present you with an agreement that they state is their "standard form", and they may request that you sign the agreement "as-is." We strongly recommend against this practice. Many "standard" consulting agreement formats may require you to submit more individual rights than are necessary to enter into a successful relationship. They may also contain language that could potentially give the company rights to intellectual property that is owned by the college. However, BCM faculty members do not have the authority to enter into agreements that transfer rights to college-owned intellectual property to third parties. If you sign such an agreement, you may find yourself in breach of the terms of the agreement. We advise you not to sign any agreement where there is lack of clarity around your individual rights or potential conflicts with the college's rights.

- **Exclusivity/non-compete clause:** The company may request that during the period in which you are a consultant for them (and for a limited period after the

consulting relationship ends), you refrain from consulting with competing companies. The scope of such non-compete clauses can be quite broad, but ideally should be limited to the specific scientific subject matter for which you will be providing consulting services. Because you are personally entering into the consulting agreement, you must decide whether any exclusivity/non-compete clause is acceptable or reasonable. You may incur personal liability if you violate the terms of your consulting contract and provide consulting services to a competing company.

- **Duration:** Most consulting agreements have a term of one to two years, which may be renewable by written consent of the parties. It is important that you understand the provisions of the agreement that survive termination or expiration of the agreement. You may still have ongoing obligations to the company after the consulting term ends (for example, an obligation to maintain the confidentiality of the company's proprietary information). You should have a right to terminate the consulting agreement after providing reasonable advance notice to the company.

- **Compensation:** Compensation for your consulting services is strictly a matter of negotiation between you and the company. The college will provide no advice around this matter. Your attorney should advise you.

- **Confidential information:** As a part of your consulting relationship, you may be given access to confidential or proprietary information belonging to the company. You will be obligated to protect the confidentiality of the company's information, and you should understand the scope of your obligations. You should not be required to maintain the confidentiality of any information that:

- Resides in the public domain in a printed publication, patent, or other tangible form anywhere in the world, or information that becomes publicly known through no wrongful act of the receiving party.
- Is known to the receiving party through disclosure from other third party sources that have the right to disclose the information.
- Was already known to you prior to the agreement, as can be demonstrated by your records.



- Is independently developed by you outside of the consulting relationship, as can be demonstrated by your records.
- Is required to be disclosed under law or governmental order.

Your attorney will advise you on the extent of the confidentiality obligations that you should accept. You must not disclose confidential information owned by the college as part of your consulting relationship—in particular, unpublished data produced by your academic research program at the college. If the company desires access to confidential/proprietary information owned by BCM, they would be required to execute a CDA with the college—your BLG project manager can assist with execution of a CDA.

- **Intellectual property rights:** As part of your role as a consultant, the company will typically require that you agree to assign intellectual property rights (patents, copyrights, etc.) developed by you arising out of your consulting activities. ***If the nature of your consulting activity is similar to your activities as an academic researcher, you must exercise care that you do not improperly confer rights to college-owned intellectual property to the company.*** Your primary employment relationship is with the college, and you need to be mindful that you don't make any commitments regarding intellectual property in a consulting agreement that you cannot honor. We suggest incorporating the following language into any consulting agreement:

"Company acknowledges that the Consultant is an employee of Baylor College of Medicine and is subject to the College's policies, including policies concerning consulting, conflicts of interest, and intellectual property. In the event of a conflict between this agreement and College policy, College policy takes precedence and this agreement shall be construed accordingly.

The company acknowledges and agrees, however, that nothing in this Agreement shall affect the Consultant's obligations to, or research on behalf of, the College, including, without limitation, obligations or research of the Consultant in connection with a transfer by the College of materials or intellectual property developed in whole or in part by the consultant, or in connection with research collaborations.

The consultant may disclose to the company any information that the consultant would normally freely disclose to other members of the scientific community at large, whether by publication, by presentation at seminars, or in informal scientific discussions. However, the Consultant shall not disclose to the Company information that is College information and is not generally available to the public other than through College formal technology transfer procedures."

DISCLOSURE SUBMISSION & MANAGEMENT

- **Ownership of Intellectual Property:** As is standard practice among academic institutions, Baylor College of Medicine owns intellectual property developed by its faculty, staff, and students. College personnel are strongly encouraged to educate themselves on the college's policies regarding intellectual property ownership and disposition. The college's Policy on Patents & Other Intellectual Property (the "BCM Patent Policy" available at: <https://mediasrc.bcm.edu/documents/2013/f0/bcmpatentpolicy.pdf>) describes these policies in their entirety, but key clauses associated with the Patent Policy are as follows:

- **Assignment of Intellectual Property Rights (Section II. A.):** "Baylor Intellectual Property is and shall be regarded as the proprietary property of the College, owned and controlled solely by the College, and all rights thereto shall be determined and administered by the College as provided in this Policy. As a condition of their appointment, employment or enrollment by, or working at the College, or use of facilities made available by or through the College, or in consideration for the compensation or other benefits received from or through the College (including the use of facilities), all College Personnel are obligated to assign and convey, and do hereby assign and convey to the College, all Baylor Intellectual Property Developed by them."
- **Definition of Intellectual Property (Section X.):** "Intellectual Property" shall mean Inventions, know-how, trade secrets, technology, research data and notes, Copyrightable Works, trademarks, service marks, and trade names."
- **Definition of Invention (Section X.):** "Invention" shall mean and include, without limitation, any development, discovery, creation, improvement or other advance whether developed as a product of mental processes or as a result of scientific investigation and experimentation, and whether not reduced to writing. Inventions shall include by way of example, but not by way of limitation: drugs, methods of healing or promoting the healing arts, chemical or biological processes or methods, gene sequences, gene therapy, cell lines, vectors, organisms, combinations of matter, computer software, electrical or mechanical devices, and electrical circuits. The foregoing examples shall not in any way limit the scope of this definition."

- **The Bayh-Dole Act and the Rise of Academic Technology Commercialization:** In 1980, Congress passed an act of legislation that made fundamental changes to the ownership and management of intellectual property resulting from federally funded inventions. The Bayh-Dole Act enabled recipients of federal research funds to elect title to inventions developed with federal funding. Universities, small businesses and non-profit organizations that receive federal research funds were now able to direct the commercialization of federally-funded inventions. Prior to passage of the Bayh-Dole Act, the vast majority of federally-funded inventions were not leveraged and developed by the commercial sector. The public funds research with the expectation that it will lead to the development of new products and services that benefit society, yet prior to Bayh-Dole, it simply wasn't happening.

The passage of Bayh-Dole unleashed a wave of commercialization activity at academic institutions across the country and spurred the growth and development of university technology transfer. Since the beginning of the Bayh-Dole era, U.S. universities have generated over 4,000 start-up companies and 153 new FDA approved vaccines, drugs and/or new indications for existing drugs were discovered through research conducted in the university setting (source: Association of University Technology Managers). It is not an exaggeration to state that the Bayh-Dole Act singularly spurred the growth and development of the biotechnology industry in the United States. The success of the Act has spawned similar legislation in numerous foreign countries, including most of the developed world's major economies.

Major provisions of the Bayh-Dole Act include:

- Recipients of federal funds, including universities and small businesses, can elect title to federally-funded innovations.
- Universities are encouraged to commercialize inventions developed with federal research funding, and are specifically encouraged to work with small businesses.
- Universities must share a portion of their commercialization revenue with the inventors of the licensed technology.
- Although universities are permitted to license federally-funded inventions to commercial third parties, the federal government retains a non-exclusive license to practice the invention in the interests of the U.S. government throughout the world.
- The federal government retains march-in rights, meaning it can step in and potentially direct activities related to commercialization of federally-funded inventions.

What to disclose? When to disclose? How to disclose?

- **What to disclose?** If you have developed a technology that solves or addresses an unmet need, you should disclose the technology to the Baylor Licensing Group. Examples of technologies that are frequently disclosed include therapeutic compositions and methods, vaccines, devices, diagnostics, software and smart phone applications, educational materials, as well as research tools such as knockout mice, antibodies, vectors, and cell lines that have been engineered to have special characteristics. Note: For the purpose of this section, the terms “technology” and “invention” may be used interchangeably.
- **When to disclose?** If the technology is one that may require the preparation and filing of a patent in order to be successfully commercialized (this group would generally include therapeutic compositions and methods, medical devices, and some diagnostics), **it is important to disclose the technology prior to any public presentation or disclosure of it. Public disclosure can take a variety of forms, including meeting abstracts, oral presentations, and online and print publications.** Many meeting abstracts are published online well in advance of the scientific meeting or conference, making it imperative to disclose the invention to BLG prior to any description of the invention appearing online. Ideally, we’d strongly like to avoid the scenario of a “rush” patent filing to try to beat online publication of an abstract, especially if there are aspects of the invention that haven’t been developed or described, such that we end up filing an application that may not adequately capture and claim important aspects of the invention.

The reason that you should disclose your technology to BLG prior to any public disclosure of the invention is linked to the fact that the ability to patent the invention in most countries in the world is permanently lost once the invention is publicly disclosed. Most countries in the world have a requirement for absolute novelty in order for an invention to be patentable. The United States does represent an exception to this practice, such that a patent application can be filed within one year of the date of the initial public disclosure—this is known as the “grace period.” However, it is important to stress that it is to your advantage, and to the college’s, to file an application before any

potential patentability rights are lost through a public disclosure.

- **How to disclose?** Submitting your disclosure is a simple process that you can do using BLG’s online disclosure submission application, available here: <https://ota.vpdr.bcm.tmc.edu/disclosuredefault.asp>, or on the front page of the Baylor Licensing Group website.

Before getting started, you’ll need the following information:

- The **names of the contributors to the technology/invention**, their contact information (if they are BCM personnel, they are searchable with the disclosure submission application), and **their respective percentage contribution to the technology.**
- The **identities of any funding sources** that were used to support the development of the technology, **including grant numbers.** BLG has reporting obligations to the federal government, and to other funding agencies (CPRIT, for example), such we must have grant numbers associated with the disclosure.
- **A description of the technology:** You may attach manuscripts, abstracts, posters, or other documents that describe the technology that you have developed; or, you may choose to write a description.

Once you have the required information in-hand, submitting the disclosure should require very little time. Once the information is submitted, you and the other BCM contributors will be asked to submit electronic signatures. BLG will coordinate obtaining signatures from any non-BCM developers. Once the disclosure has been submitted and transferred to the BLG database, you will receive an email confirmation and your department chair will be notified as well.

■ Disclosure Management: What Happens to Your Disclosure?

- Following submission of the completed disclosure, it will be assigned to a BLG project manager, who will work with you to determine the appropriate commercialization strategy. Each BLG project manager is responsible for managing disclosures from a portfolio of departments, as shown on **TABLE 2.**
- The typical workflow of the disclosure management process is summarized in “Life Cycle of an Invention Disclosure” (**FIGURE 1**). The individual steps in this process are described

TABLE 2: BLG Project Manager Department Portfolios

Licensing Department Responsibilities			
Terese Rakow, Ph.D.	Lisa Beveridge	Mercy S. Chen, Ph.D.	Brian Phillips, Ph.D.
Molecular and Human Genetics	Molecular and Cellular Biology	Center for Cell and Gene Therapy	Pediatrics
Molecular Physiology	Neuroscience	Molecular Virology & Microbiology	Pathology/Immunology
Medicine, Section of Endocrinology	Neurology	Medicine (Most Sections)	Pharmacology/Center for Small Molecule Discovery
Ophthalmology	Neurosurgery	Biochemistry	Physical Medicine & Rehabilitation
Otorhinolaryngology	Surgery	Human Genome Sequencing Ctr.	Ob-Gyn
Lester & Sue Smith Breast Center	Psychiatry	Huffington Ctr. on Aging	Radiology
Anesthesiology	Orthopedic Surgery	Urology	Dermatology
	Dan L. Duncan Cancer Center	Center for Reproductive Medicine	Family & Community Medicine
		Center for Education Outreach	School of Tropical Medicine
		Center for Ethics	Center for Vaccine Development
		Center for Comparative Medicine	Student Affairs (Med Students)

in detail in this guide (marketing and licensing activities, for example), but this graphic serves to provide a schematic overview of the entire process beginning with the submission of a disclosure and ending with the successful execution of a license agreement or a decision to

close the file and cease licensing and marketing activities.

- **Invention Disclosure Analysis: Elements & Purpose.** Once your disclosure is assigned to your BLG project manager, they will initiate the

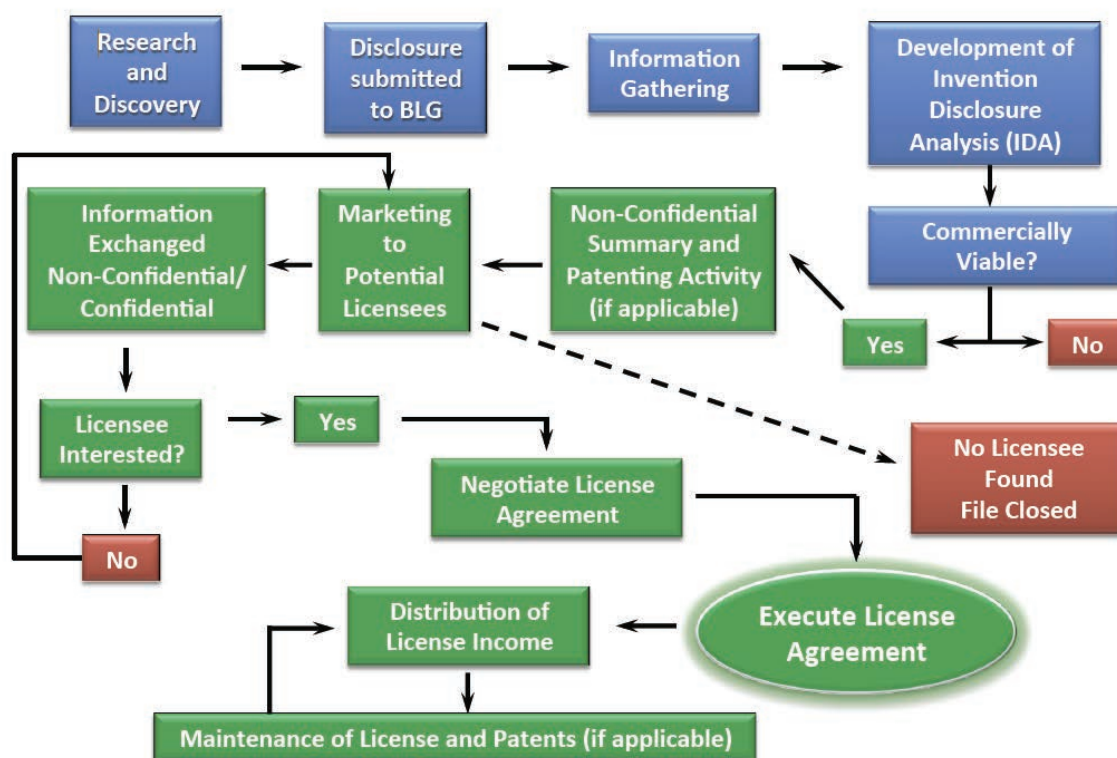


FIGURE 1: Life Cycle of an Invention Disclosure

process of coordinating the development of an Invention Disclosure Analysis (IDA) for your disclosure (**Figure 2**). The IDA is intended to provide the faculty member with an analysis of factors that impact the commercial prospects of the disclosed technology and it will provide a commercialization recommendation along with a rationale for the recommendation. The IDA is not intended to be an exhaustive analysis of the disclosure, but is intended to be a vehicle to provide high-quality feedback to the PI within a reasonable timeframe after submission. The IDA process will be initiated when the BLG project manager has received sufficient information on the technology to conduct an evaluation. Members of the BLG intern team will assist BLG project managers with the collection of prior art and market information that is relevant to the invention being analyzed.

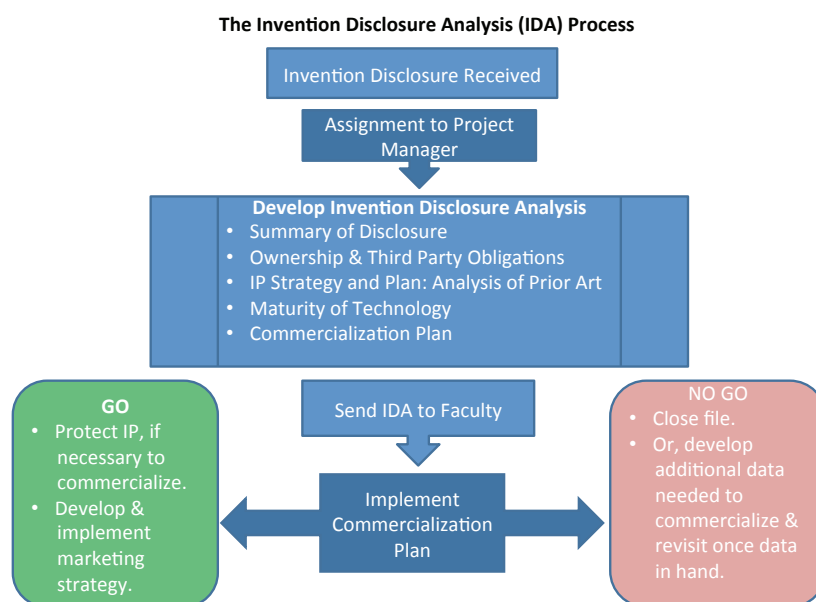


FIGURE 2: The IDA Process & Outcomes

Elements of a typical IDA will include:

- A ***description of the technology*** being evaluated.
- ***Citations of prior art*** in the scientific and patent literature that are relevant to the invention, along with citation of specific language/passages in the references that may read upon aspects of the invention.
- A ***description of the commercial market*** associated with the invention, which may contain a list of companies/products that are active in the relevant market, and/or descriptions of competing technologies.
- ***Identification of any encumbrances*** that may impact our ability to commercialize the disclosed technology. Such encumbrances might consist of obligations to third parties that arise via previously signed agreements, such as MTAs or SRAs.
- A ***commercialization plan***, which may result in a decision to prepare marketing materials and begin marketing the invention to potential licensees, and/or to prepare and file a patent application. Alternatively, we may decide that the invention has already been substantially disclosed in the prior art and we may elect not to file a patent or to market it to industry. Each technology will be different, and the commercialization plan for each one will be different as well.

■ Typical Commercialization Factors & Strategies for Different Types of Inventions (**FIGURE 3**)

Each technology disclosed to BLG will be examined on its own merits, but there are some general factors that impact the commercialization prospects, and our decisions around them, for different classes of technologies:

- **Therapeutic Methods and New Uses for Existing Compounds:** In order for a therapeutic method to be of interest to a potential licensee, they will typically wish to see proof-of-concept data from a relevant animal model system. If the therapeutic method involves the use of a compound/molecule that is owned by a third party and not BCM, then the likely (and in most cases, the only) prospect for a licensee will be the owner of the compound. There has been much focus and emphasis on developing new uses for existing compounds. For a compound that has already been through the regulatory approval process and has been proven safe for use in humans, there are sound reasons to investigate new uses for it from a patient care standpoint. But, from a commercialization standpoint, ***the company that owns the compound will be the primary beneficiary of any new method of use for such a compound that is developed by an academic PI.***

If an academic PI develops a new method of use for an off-patent, non-proprietary FDA-approved compound, it is often very difficult to attract a company to license such a technology because

the compound itself is no longer protectable, and enforcing infringement around a new method of use for a non-proprietary compound is challenging at best, particularly if the new method of use can be achieved via “off-label” use of the approved drug.

Technologies involving novel therapeutic methods that are not associated with some sort of proprietary molecule or compound are very tough to successfully commercialize. There must be some aspect of the data associated with the new method that is extraordinary in some respect to have a realistic shot at garnering commercial interest.

There are cases in which a new therapeutic method is developed using an existing compound, but a route exists by which potentially proprietary derivatives can be developed. We often will elect to file a patent application under these circumstances, provided that the PI has a plan in place to develop and enable such derivatives, and provided that there is indeed a real prospect for developing derivatives that have not been described or claimed by a third party. We will use outside patent counsel to guide strategy.

- **Therapeutic Compounds or Molecules:** When we receive a disclosure that describes a potentially proprietary composition of matter, our initial focus will be to determine whether the molecule is indeed novel and proprietary, or whether it is based upon a known composition or molecular scaffold. We will also be interested in determining the degree to which derivatives can be made, claimed, and tested. If at all possible, we would prefer to file a patent application once the compounds/molecules have been tested in an appropriate animal model system, so that we can claim both the compound(s) and methods for their use in treating disease.
- **Drug Targets:** Disclosures based on genetic or biochemical evidence that a gene/protein constitutes a route for the development of a therapeutic (a “target”), but lacking any description of a molecule that interacts with and impacts the activity of the target are extremely difficult to successfully commercialize. We do not file patent applications on disclosures that describe drug targets without a description of a molecule that interacts with it. Nor do we file patents with claims directed to screening methods because screening method claims are very difficult to police for infringement and

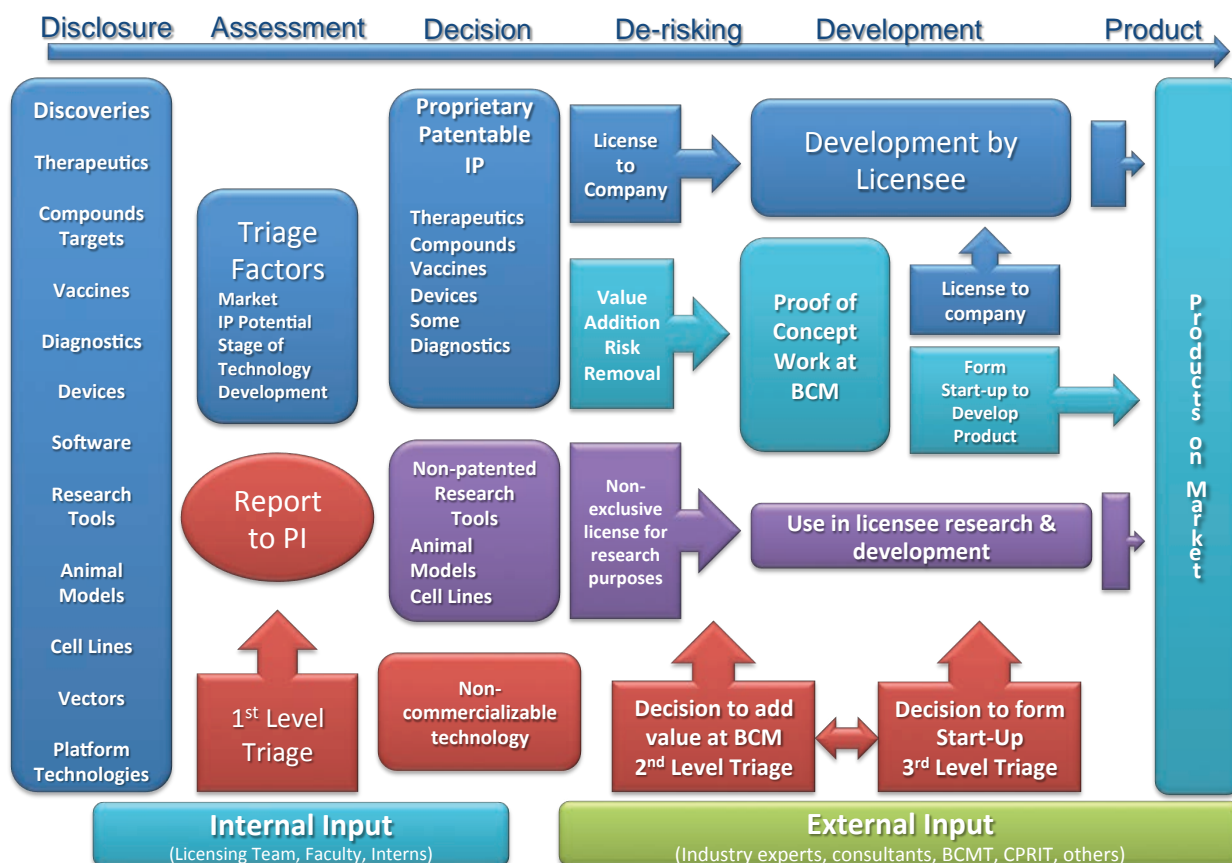


FIGURE 3. Technology Commercialization at BCM

companies won't license screening method patents. We cannot obtain patent claims to a molecule that interacts with a target without providing an enabled example of such a molecule. There is legal precedent around this issue (*University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004)). In this high-profile case, the court ruled that a patent held by the University of Rochester that claimed inhibitors to the Cox-2 enzyme without actually providing an example of such an inhibitor was invalid.

It is very difficult to find a commercial partner if all we have to offer is a target without a molecule. Once information about a target is published, any third party can use that information to develop a screen and isolate a molecule. If you have developed data on a target that you believe is proprietary, you may wish to pursue collaborative routes to develop a molecule that interacts with your target. The BCM Center for Drug Discovery may be able to help you identify collaborative routes to isolate a molecule that interacts with your target.

- **Diagnostic Tests/Biomarkers:** The key question to answer regarding the commercial prospects of a diagnostic test or biomarker is: "How will the information gained from this test inform the patient's healthcare professional and change the course of treatment?" If the test doesn't change the patient's course of treatment or clinical outcome, then its commercial prospects are probably insignificant. If indeed the diagnostic test does change the course of treatment, then the focus of the evaluation will shift to the identification of aspects of the test that are proprietary (novel sequences, antibodies, reaction conditions, etc.).

Additionally, a recent case decided by the Supreme Court (*Mayo v. Prometheus*) held that measurement of a metabolite and the use of that measurement to guide treatment did not constitute a patentable invention because the test revolved around measurement of a metabolite existing in the natural state without any transformative step. The outcome of this case has thrown patents with claims directed to diagnostic methods in to a state of confusion, and companies have become more hesitant to license diagnostic technologies.

Because of Baylor's extraordinary strength in the genetics of rare diseases, particularly neurological disorders, we do receive disclosures of diagnostic tests for these rare disorders. Our current practice is to rarely, if ever, patent diagnostic tests to rare genetic disorders. The target markets and patient populations are often very small with limited commercial prospects. Additionally, patient access

to these tests has become a prominent issue via the activity of patient advocacy groups, such that the exclusivity associated with patenting the test may run counter to the focus of advocacy groups who desire broad dissemination of such tests.

- **Medical Devices:** Our evaluation of the commercial prospects associated with a medical device technology will revolve around obtaining answers to the following questions:
 - Is the device design technically feasible? Does a prototype of the device exist? Are there means to develop/test the prototype?
 - If a prototype has been developed, has it been tested in an appropriate animal model system?
 - Is the device novel & proprietary? Does the device represent an incremental improvement of an existing device approach, or is it a new design? Ease of workaround may be a significant issue if the device is more incremental vs. completely novel.
 - How does the device differ from other current solutions for the same application? How does the new device stack up against the "gold standard"?
 - Does the device depend on or interface with other technologies/devices in order to be used? Does the device require software to work? If so, who owns these other required technologies?
 - Is the device cost-effective? Can it produce an improved patient outcome at a lower cost than other current solutions on the market?

- **Research Tools**

Research tool technologies include tangible materials such as mouse models, cell lines that have been engineered or selected to have specialized characteristics, expression vectors, bacterial strains, etc. If the tool that you've developed is popular with your academic colleagues, there is a good probability that it may be of interest to scientists in industry as well. We don't patent research tools—the goal of research tool licensing is to promote the broad adoption and use of the tool via a non-exclusive licensing strategy. Companies will readily pay for access to research tools that will add value to their research programs. Licensing a tool saves the company the time and resources that it would have to commit if it were to decide to independently develop the same (or a similar) tool.

A peer-reviewed publication that describes the use of a tool is often the best route for marketing a tool to industry. We frequently coordinate our marketing efforts to coincide with publication of manuscript that describes the tool.

– Software/Smart Phone Applications

Software technologies are frequently protected by registration with the U.S. Copyright Office vs. filing a patent application. The software development cycle is typically very fast, whereas the patent prosecution process takes years, and by the time that a patent issues, the claims may no longer be relevant to the current version of the software. Registering the code with the copyright office is generally the preferred route for protecting a software application against potential third party infringement. There may be cases in which the software is built around a proprietary algorithm that may warrant patent protection, but this is generally the exception and not the rule.

In terms of commercial prospects, our evaluation will focus on the aspects of the software that differentiate it from competing software applications. What features and capabilities does the software application have that others lack?

In recent years, we've begun receiving disclosures from smart phone applications. We are encouraged to see these new digital innovations from the BCM research and clinical communities. However, most of these apps tend to be of interest to very specialized niche markets, and generally don't represent significant commercial opportunities. They are often best disseminated on marketing channels such as iTunes. There has been active discussion about different strategies to commercialize smart phone apps in the academic technology transfer community, and we are also

exploring and considering suitable solutions for healthcare related apps developed at BCM.

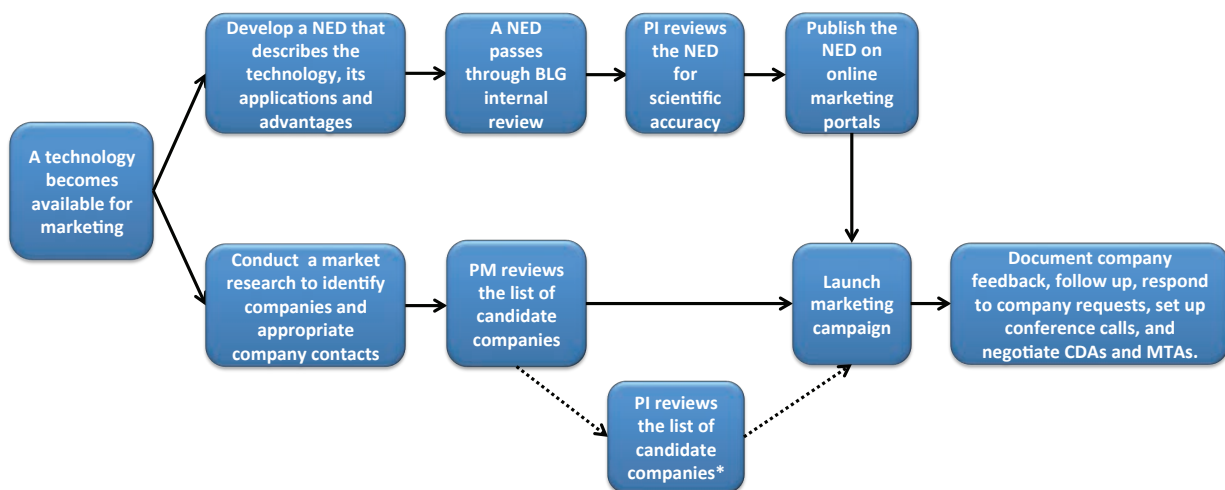
MARKETING

It's a partnership: Our most successful licensing transactions have almost always involved teamwork between the PI and their BLG Project Manager working in tandem to find the best commercial partner for development of the technology. As a faculty member, you have deep expertise in your field of study, and you will often know who the key industry players are in your field of study. You may have friends or colleagues who are scientists in industry. Those relationships are frequently the basis for subsequent collaborations and licensing relationships. Many successful licensing transactions (particularly those involving proprietary patented technologies) will open the door to long-term relationships that involve far more than a mere hand-off of technology and/or patent rights.

BLG MARKETING EFFORTS

Once a decision is made to begin marketing a technology, the following steps are usually taken [these can vary depending on circumstances associated with a particular technology (**FIGURE 4**)]:

- **Preparation of a non-confidential marketing summary (a "NED" = non-enabling disclosure):** NEDs are short 1-2 page documents that describe the problem addressed by the technology, the technology solution to the problem with a focus



Footnotes:

* May not apply to all technologies.

NED: non-enabling disclosure; **PM:** BLG project manager; **PI:** Principle Investigator

FIGURE 4: BLG Technology Marketing Process

on advantages and applications, and information about publications and patent applications describing the technology.

- **Identification of potential licensees:** The IDA will often provide the identities of companies that we think are logical marketing targets for your particular technology. We employ a “rifle-shot” approach to marketing, meaning that we focus on contacting those companies with research and/or product development programs that we think are most closely aligned with the technology being marketed.
- **Contacting potential licensees:** We will identify a contact person within the company of interest and send non-confidential information to them for review by the company. We will also request feedback from the company so that we can understand the factors that are relevant to their interest (or lack of it) in the technology.
- **Execution of a confidential disclosure agreement (CDA):** If a potential licensee is interested in additional information about a technology that extends beyond the available non-confidential information, they may agree to sign a confidential disclosure agreement (CDA). Once a CDA has been executed, we can share confidential information (unpublished data or unpublished patent applications, etc.) with the company to augment their evaluation process.
- **Online marketing portals:** In addition to our target-specific “rifle-shot” marketing efforts, we would also like to build worldwide awareness of our innovative technologies. To that end, we market technologies on globally accessible web marketing portals, including:
 - **Association of University Technology Managers (AUTM) Global Technology Portal (GTP).**
The GTP is a relatively new online technology marketing portal developed by AUTM, the professional association that encompasses academic technology transfer. Numerous technology marketing portals exist, but we think there is a good probability that this portal will develop enough critical mass to become an effective tool.
 - **BLG technology marketing webpage.**

PI MARKETING EFFORTS

As a PI and developer of a technology, you are well-positioned to be a catalyst for landing a licensee and developing a successful relationship with them. It is important to emphasize that most licensing transactions involving therapeutics and devices will form the foundation for a long-term relationship between the company, the PI, and the college. Your

networking efforts may be the deciding factor in securing a licensee to develop your technology into a product. You will have opportunities via multiple routes to market the technology that you’ve developed.

These routes include:

- **Relationships with colleagues in industry:** Your scientific colleague in industry can be an effective internal champion to spur a research collaboration or license agreement. These relationships are often critical in the company’s decision-making process. If a company scientist approaches his/her business development colleagues with a need to acquire rights to a technology from a third party, and if they successfully demonstrate why it is necessary for the company to access the technology, this can be the catalyst to getting a deal done. It is very rare occurrence that a company will decide to in-license a technology in the absence of a relationship around it, or in the absence of the technology being identified as a strategic need. Once a company determines that they wish to acquire rights to a technology, they’ll seek out third party institutions and scientists that have the needed expertise and/or technology. Company decisions are always driven by bottom-line financial considerations – in order for a license agreement or sponsored research agreement to be executed, the company must have funds budgeted for this purpose.
- **Scientific conferences:** These events provide excellent opportunities for you to meet and talk with industry colleagues. In order to be an effective advocate for your technology, consider doing the following:
 - **Prepare an elevator pitch:** Be prepared to describe your technology in lay terms—describe the problem that it solves, and how your approach is better, faster, or cheaper than current solutions on the market. Be clear and succinct—keep the pitch to around a minute.
 - **Don’t hit them with too much data:** You are the expert and you know your technology in depth, but during initial conversations with industry personnel who may have different backgrounds, it is important to avoid overwhelming them with too much scientific detail. Limit your focus to a couple of key pieces of data that demonstrate the capabilities of your technology. Focus on the result that you are most excited about.
 - **Listen:** Take time to understand what your industry colleague’s needs are—why are they interested in talking with you? What are they seeking to gain from the interaction? Is there an opportunity for a mutually beneficial relationship?

- **Have additional information ready:** Take copies of the non-confidential summary that describes your technology and distribute it. Copies of published manuscripts may be useful as well. Exchange business cards (and keep your BLG project manager in the loop regarding your business contacts). Be careful not to share any unpublished data or information with a company, or any other third party.
- **Be patient:** From the time that a relationship with a company begins, it may take a period of months or years before the company actually decides to move forward with a license or research collaboration. During this interim period, continue to cultivate relationships that have the potential to be mutually beneficial and productive.

- **Publication:** Publication of your work in a credible peer-reviewed journal provides a fantastic marketing tool because it demonstrates to industry scientists that your work has been vetted and validated by your academic colleagues. Companies will often wait to make a decision about their level of interest in a technology until a peer-reviewed publication appears online. Part of the reason for this is that they may want to see validation of your work by your colleagues, but confidentiality concerns may be at play as well. Once the manuscript is published, it is obviously no longer a confidential document and the company has no requirement to sign a confidential disclosure agreement in order to review it. Companies may be reluctant to sign a CDA if they have an internal research program that is similar to, or may overlap with, the research program of an academic PI.

For research tools, our marketing efforts will frequently coincide with the publication of a manuscript that describes the use and characteristics of the tool. A publication describing the use of a tool is essential to stimulate commercial interest in it.

LICENSING

When a company approaches BLG and states that they want to enter into a license agreement, a period of negotiation begins during which both parties work to arrive at a mutually acceptable deal. Some licenses are negotiated and completed in a manner of weeks, whereas others may take many months. Our goal is to get promising technology invented by BCM PIs into the commercial sector where it can be further developed, and to achieve this we take a practical, pragmatic, principled approach to license agreement negotiation.



The route to an executed agreement typically involves the following negotiation process:

- **Preparation of a Term Sheet:** A Term Sheet is a 1-2 page document that describes the framework of the transaction, and includes the following elements:
 - **Description of the rights being licensed:** The intellectual property rights being licensed can involve a variety of assets, including:
 - **Patent Rights:** In most cases, we will be licensing a patent application vs. an issued patent. The term sheet will incorporate description of the patent rights being licensed, which includes bibliographic information such as the serial number of the patent, the date it was filed, names of the inventors, and any patent applications that claim priority to the original application, etc.
 - **Technology Rights:** Technology rights may include tangible materials, biological reagents, data, specialized know-how or other information that the licensee may need to commercially develop the invention. We will develop a list of specific items encompassed in the technology rights that we intend to provide to the licensee.
 - **Scope of the license:** This part of the term sheet will define whether the license will be exclusive or non-exclusive, will also define whether the granted license will be limited to a specific field of use, or to a specific territory.
 - **Financial terms structure:** This section focuses on the fee structure associated with the license, which can include a combination of upfront and/or recurring fees, as well as a royalty on

net sales of licensed products or services, as appropriate. Negotiation of the fee structure of a license involves compromise on both sides to arrive at an acceptable deal structure. If a company is licensing a promising preclinical, but as yet unproven technology, their focus around fee negotiation will be to defer the payment of substantial fees to the licensor until the technology is de-risked and validated. From our standpoint as a licensor, we want to receive some financial consideration early during the life cycle of the license as a demonstration of good faith and commitment. Moreover, if the licensee fails to successfully develop the technology, those early stage fees may be all that we will ever receive.

As is the nature of academic inventions, most technologies we have are in the early phase of development and the licensee will have to assume large risks in the commercialization process. Because of this reality, the frequent end result is that most license fee structures are back-end loaded, meaning that fees during the early stages of the license life cycle are modest, and increase as value is added to the technology and risk is removed. It is important to emphasize that each technology is different and each deal structure will be the product of a unique negotiation.

- **Diligence terms:** Our goal with licensing is to translate innovative research discoveries into products and services that benefit patients and the general public. The incorporation of diligence terms is meant to convey expectations and to incentivize the licensee to exercise good-faith diligence with the development of the licensed technology. Diligence terms may involve targeted timelines for the achievement of developmental milestones. An example might be: “Licensee shall file an IND application with the FDA on a Licensed Product within five years of the license agreement date.” As a licensor, we’re seeking diligence terms that are clear, unambiguous and will keep the licensee moving forward.

Because the licensee stands to reap the lion’s share of the reward if commercial success is achieved (which is appropriate because they’re also assuming a great deal of risk and making a considerable financial investment), they’re typically very strongly motivated internally to move development of the technology forward. Agreement upon diligence terms is a matter of negotiation. As a licensor, we want clear and enforceable diligence terms, such that there

are real consequences to the licensee if they miss a diligence target. From the company’s perspective, they don’t want to be in the situation of facing potential termination of a license agreement if they miss a diligence target, but have in fact made good-faith efforts to develop the technology. Priorities within companies can change, and if that does happen, the company can opt to terminate the license agreement.

The incorporation of an annual maintenance fee in to the financial structure of an agreement can provide an incentive for the licensee to continue developing the technology. If the company has to write a check each year in order to maintain the license, they are in the position of having to make a financial decision about holding on to the license on an annual basis.

■ **Agreement on the business terms and license framework presented in the term sheet, followed by preparation of a draft license agreement.**

Once a term sheet has been developed, both parties will negotiate over the business and diligence terms and arrive at a mutually acceptable framework that will be incorporated into a full draft license agreement. We strongly prefer to use our license agreement templates as starting points because we own the intellectual property that is being licensed. Once drafts have been exchanged, additional negotiations over the terms of the license agreement will commence.

The negotiation period is variable, and is typically shorter for non-exclusive research tool licenses, and longer for exclusive agreements involving rights to therapeutics, devices, or vaccines. The negotiation period depends heavily on the negotiating partner on the other side of the table. In many cases, companies will send a draft license agreement to their legal counsel for review. If the company’s legal counsel has experience working with academic institutions and understands their concerns, the negotiations may proceed smoothly. If not, it can be a very different story and negotiations can drag on, which is never our goal. However, we are charged with protecting the interests of the college and there are times when the other party may insist that we agree to terms that we believe may be harmful to the interests of the college, and resolving these issues can be challenging. The point is to end up with a mutually acceptable deal that gives both parties sufficient incentive to move forward. Unbalanced, asymmetric deals that unacceptably favor one side

over the other never work out well in the long run. So long as there is sufficient will to execute a deal on both sides of the table, and both sides stand to gain from reaching agreement, agreement will be reached. Each license agreement is the product of a unique negotiation—no two are exactly the same.

■ **Legal review and signature of the license agreement.**

Once agreement on license terms and language has been reached, the draft agreement will be sent to the BCM Office of General Counsel (OGC) for legal review. This legal review process focuses on license agreement terms that could potentially expose the college to undue risk, etc. BLG project managers have experience working with OGC, so in most cases if there are questions about particular agreement terms, those questions are addressed and resolved prior to the agreement being submitted for final review. After the agreement passes OGC review, it is forward to the Sr. VP for Research for signature on behalf of BCM. Following signature by BCM, the agreement is forwarded to the company for final execution. Once both sides have signed the agreement, the deal is fully-executed.

■ **Types of license agreements**

- **Exclusive licenses.** These agreements involve a license of intellectual property rights to a single company, and typically involve a patented asset – a therapeutic (drug, biological, method, or some combination), a device, or a vaccine. The licensee is granted the exclusive right, often with the right to grant sublicenses, under patent and technology rights owned by BCM, to make, have made, use, market, sell, lease, and import licensed products in the field of use. The license grant that we confer to companies allows their commercial exploitation of the technology. However, the exclusive license grant is restricted and non-exclusive with respect to the following terms:

- BCM will always retain the right (for itself and others) to use the licensed patent rights and technology for non-commercial research and education purposes, as we can't accept terms in a license agreement that impede or restrict the ability of the PI to continue their academic research. If, however, the technology being licensed is in clinical development, the licensee may insist that they have the right to approve any clinical use of the licensed technology in the academic setting. The reason for this is that if clinical use of the technology in the academic setting were to result in an

adverse event, it could derail the company's commercial development efforts and would be very costly to the company.

- If the licensed technology was funded by the federal government, we will stipulate that the government has a non-exclusive right to use the invention by or on behalf of the United States. This is a statutory requirement mandated by the Bayh-Dole Act.

- **Financial consideration in an exclusive license:**

Financial terms in each license agreement are a product of a negotiation and can vary widely from deal to deal. The following elements are frequently found in exclusive licenses:

- **Upfront payment:** Due upon execution of the license.
- **Annual maintenance fee:** Due upon each anniversary of the license agreement.
- **Milestone fees:** Fees that are payable upon the successful achievement of a commercial development milestone, for example, the initiation of a phase II clinical trial of a licensed product. When a licensee achieves a milestone event, they have an obligation to report the event to the licensor and accompany it with the appropriate payment.
- **Royalties on net sales:** Royalties are recurring payments (typically quarterly) based on a percentage of net sales by the licensee.
- **Other fees** or variations on the fees listed above may be a part of the deal.
- **Equity:** BCM does accept equity in license agreements to start-up companies. Start-ups are typically cash-poor and cannot afford extensive cash fees at the outset of the license life cycle. They're trying to raise money, not spend it. Most deals that involve equity also have cash fees (milestones and royalties) associated with them, so that the prospect of receiving consideration from the licensee isn't solely dependent on the equity becoming liquid. Equity is distributed under the terms of Patent Policy in the same manner as cash consideration, meaning that as a faculty member if the license involves equity as part of the compensation package, you will receive your shares upon issuance (usually shortly after execution of the license). Your shares will be yours to manage, and any decision to sell or dispose of your shares will be yours – the college will manage its shares independently.

- **Other key elements of an exclusive license agreement:**

- **Indemnification:** BCM requires its for-profit licensees to indemnify the college and its

personnel against any third party legal actions that may arise out of the licensee's activities under the license agreement. This is an issue that is critically important to the college. If a licensee attempts to change the indemnity provisions of the agreement to shift risk in the college's direction, this can produce delays with concluding an agreement.

- **Insurance:** BCM requires its licensees to carry adequate insurance protection that is appropriate for the type of product being developed and/or marketed by the company.
- **Management of infringement actions:** Describes how the licensee and licensor will address any actions related to third-party infringement of the licensed patent rights, and describes how any infringement related settlement will be allocated among the parties.
- **Term and termination:** Defines the lifespan of the license (for a patented technology, the deal will typically expire when the last-to-expire patent claim expires in a particular country). This section also defines the circumstances under which BCM as a licensor can terminate the licensee. Our right to terminate is typically linked to a breach by the licensee that is not cured within a specified period of time. The for-profit licensee can terminate the agreement with or without cause. If the company decides that their strategic priorities have changed and they no longer wish to develop the technology that they licensed from BCM, they may elect to terminate the deal.
- **Non-exclusive license agreements.** These license agreements involve technologies that are licensed to multiple companies, and most frequently confer rights to non-patented research tools, such as knockout mice, cell lines, antibodies, and the like. The license grant will often be restricted to research use (frequently the case with mouse licenses), or the license may convey the right to sell the licensed technology to third parties (as may be the case when we license an antibody to a distributor of life science research reagents).
 - **Financial consideration in a non-exclusive license:**
 - **Upfront payment:** Once the upfront payment is received, the PI is provided with instructions for shipping the material to the licensee. In some cases, compensation for research tool licenses may be limited to a single up-front payment, if appropriate. Most research tool licenses will involve an upfront payment and an annual maintenance fee.
 - **Annual maintenance fee:** This fee, as the name implies, is payable upon each anniversary of the agreement, typically for the duration of time that the licensee intends to use the tool.
 - **Royalty on net sales:** This recurring fee is applicable in cases when a tool is licensed to a distributor of life science reagents for resale to their third party customers (often the case with antibodies). As a matter of practice, we do not seek “reach-through” royalties on products that are developed with the use of our tool. For example, if we license a mouse model to a pharmaceutical company for use in their drug screening efforts, we would not expect to receive a royalty on any compound that touched the licensed mouse at some point during the drug development process. Seeking a reach-through royalty associated with the use of a tool is a “non-starter” for pharmaceutical and biotech companies, and is a mechanism to insure that a deal won't get done. The company will walk away and find another route to get what it needs.
 - **Lack of patent costs:** Because research tools are almost always not patented, there are no patent costs to reimburse before license revenue distribution to the PI, department, and BCM General Fund can take place. For popular research tools, the revenue stream to the PI can be significant.
- **Inter-institutional Agreements (IIAs)**

We live and work in a collaborative world, and technologies are frequently developed that are co-owned by two (or more) academic institutions. In order to successfully commercialize a co-owned technology, academic institutions will frequently negotiate an inter-institutional agreement (IIA) to put the technology transfer office of one of the owners in the “driver's seat” with regard to the management of licensing and patent strategy. The institution that assumes the lead commercialization role typically has the authority to coordinate patent prosecution strategy and to negotiate a license agreement on behalf of both institutions. The institution that takes the lead role is normally the one that owns the majority of the jointly-owned technology. The parties to the IIA will agree upon patent expense sharing and license revenue sharing and these percentages almost always coincide with each institution's respective ownership percentages in the invention. In most cases, the negotiation and management of IIAs is a

collegial process, as it should be given that both academic owners of the technology want to see it successfully commercialized.

IAs are done to facilitate more efficient commercialization of jointly-owned inventions. If a company had to negotiate a separate license agreement with each academic institution that had ownership rights to an invention, they might simply choose to walk away rather than deal with the transactional complexity of completing multiple deals to sew up rights to the invention.

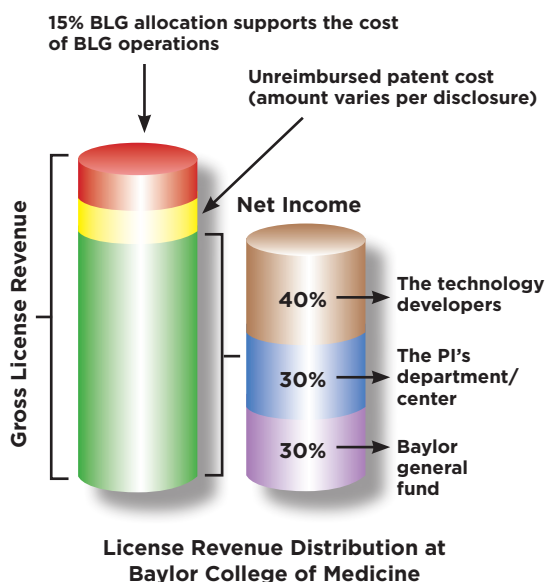
■ **Distribution of license agreement revenue**

The license revenue distribution scheme at BCM is defined in Section V of the BCM Patent Policy (BCM Policy Manual, “Inventions & Patents”, Policy 20.8.1). The distribution scheme is as follows:

Gross license revenue – 15% BLG allocation – unreimbursed patent costs = Net Income

1. 15% of gross license revenue is allocated to BLG to support the cost of our operations.
2. Any unreimbursed patent costs are paid back. We attempt to negotiate repayment of past patent costs by licensees, but this is a matter of negotiation.
3. Arrive at Net Income
 - a. 40% of Net Income is allocated to the developers according to the percentages listed on the disclosure form.
 - b. 30% of Net Income is allocated to the department/center where the technology was developed. Note: If a PI has academic appointments in multiple departments at BCM, it will be important for the PI to identify the appropriate departmental affiliation for the disclosed technology, so that the departmental share of license revenue can be correctly allocated.
 - c. 30% of Net Income is allocated to the Baylor General Fund.





The license revenue distribution policy at BCM is consistent with best practices across academia. Generally, academic revenue distribution policies divide license revenue among the inventors, the department, and an institutional research fund, but there is broad spectrum at play. BCM's policy fairly recognizes the role of the inventor, as well as the support of the department and the institution. The college fronts patent costs and coordinates patent prosecution activities, so there is no risk to the inventor associated with these activities. In contrast with their academic colleagues, industry scientists generally do not directly share in the revenue that their invention(s) produce for their employer. When a BCM invention is successfully commercialized, everybody wins.

In case of a jointly-owned technology, license revenue will be shared with the other institution, normally at a level that is proportional to the other institution's ownership interest. If required in the funding agreement, we may also share license revenue with non-profit foundations and other research sponsors, and here the revenue sharing percentage is typically in alignment with the degree to which the foundation's funding was used to support the development of the licensed invention.

■ Post-license agreement management

The execution of a license agreement should not be thought of as an ending, but rather as the

beginning of a long-term relationship. During the course of that relationship, there are several parameters that are monitored by BLG:

- **Timely submission of payments:** BLG monitors licensee payments and notifies licensees when they are late. When interest is owed, we notify them that the owe interest as well. Many licensees require that BLG prepare and submit an invoice for payment, which we do. We do have recourse if a licensee does not pay, leading up to and including termination of the license agreement.
- **Achievement of diligence milestones:** BLG monitors the progress of our licensees as they work to develop from products and services from the licensed technology. Licensees don't always hit their diligence targets, and in fact, "misses" are frequent. Developing products based on biological technologies is often a very complex, time-consuming process, and despite a licensee's best efforts, they may miss a diligence target. Our key goal is to insure that the licensee is indeed exhibiting a good-faith effort to develop the technology and move it forward.
- **License amendments:** An executed license agreement is a binding legal agreement between the parties. That being said, because license agreements govern long-term relationships and the parameters that impact a license agreement can change during the life cycle of the agreement, it can be necessary to amend limited terms for a compelling reason and upon mutual agreement between BCM and the licensee. Amendments may be necessary to add new intellectual property to the list of licensed IP, to change a diligence target, or to change the financial terms of an agreement. A company may encounter a situation in which they are no longer able to meet the financial obligations associated with the license agreement, and they may wish to renegotiate to avoid possible termination of the agreement. If it makes sense for the commercial prospects of the underlying technology, then we may agree to renegotiate the financial terms of a deal, but any such renegotiation must make sense for BCM, as well as the licensee.



PATENT STRATEGY: The patent decision-making and prosecution process explained

Introduction: The goal of the commercialization process is a license that leads to commercial use or development of the technology/invention, and not to obtain a patent *per se*. We make the decision to file a patent when we believe that patent protection is necessary to stimulate commercial interest in an invention so that we can successfully land a licensee. The types of inventions that we most frequently patent are therapeutics (molecules & methods), devices, and vaccines. The decision to file a patent application on an early-stage, but promising invention represents a calculated risk on our part that we'll be able to find a licensee for it. In some cases taking that risk is rewarded and we license the invention, and in others it is not, and the underlying reasons vary from case to case. Patent protection, and the exclusivity that comes with it, is necessary to stimulate a company to expend the resources that it will take to develop an invention and to shepherd it through the regulatory approval process.

- **What is a patent?** A patent is a document granted by a governing body that confers an exclusionary right to an inventor to make, use, and sell the invention claimed in the patent for a set time period. In the United States, the basis for the patent system is described in Article 1, Section 8, Clause 8, of the U.S. Constitution, which states: "The Congress shall have the power... To promote the progress of science and

the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries;" The fact that a patent is an exclusionary right means that the patent holder has the right to exclude others from practicing the claimed invention, but it does not guarantee the patent holder the right to practice the invention.

For example, an inventor develops an automated navigation system for a car to allow a car to be operated without a driver. The inventor files a patent application and obtains an issued patent with claims directed to an automobile containing the automated navigation system. Other parties, like car manufacturers, have patents with claims directed to automobiles, so the inventor of the automated navigation system can't manufacture cars containing the navigation system without obtaining licenses to the third party patents claiming automobiles. But, the inventor has the right to exclude anyone, including these holders of automobile patents, from manufacturing cars containing the claimed navigation system. This is what is meant by the exclusionary right—the patent holder doesn't necessarily have freedom-to-operate with the claimed invention if there are third-party patents covering other components of a final product, but the inventor can exclude others from practicing his/her claimed invention in a product in the absence of a license agreement with the inventor.

- **Basic patent strategy considerations.** The goal of the patent prosecution process is to prosecute and obtain claims that would be of interest to a commercial licensee. The patent must add value to the invention in a manner that is necessary to induce commercial investment in it.
 - Claims that describe the invention in ways that are relevant to how it will be marketed and sold (pharmaceutical compositions, formulations, kits, devices, etc.) by a commercial licensee are optimal. We are most likely to receive clearly enforceable claims if the claims cover a composition of matter comprising the invention.
 - Claims that only describe an invention in terms of methods for using it may be more challenging to enforce and easier for third parties to work around. Therefore, they generally aren't as valuable to a licensee as composition of matter claims.
 - As a matter of practice we don't patent research tools—genetically engineered mice, cell lines, etc. If the tool is useful, the goal is not to exclude use, but rather to promote it and disseminate the tool widely. This goal is

consistent with NIH guidance on the sharing of model organisms. BCM controls access to the tool, and by pricing the tools realistically, we find the companies will readily pay for access to tools and reagents that add value to their R&D efforts.

■ **Patentable subject matter.**

In order for an invention to be patentable, it must meet the following criteria:

- **The invention must be patent-eligible subject matter:** This provision essentially stipulates that “anything under the sun made by man,” can potentially be patentable. Non-patentable subject matter includes:
 - Laws of nature.
 - Natural phenomena.
 - Abstract ideas.
- **The invention must be novel:**
 - The novelty requirement means that for an invention to be patentable, it must not be described in a prior art reference anywhere in the world. If a patent examiner rejects an invention on the basis of novelty, the applicant must describe how the new invention differs from that of the prior art. Many inventions, particularly in the device field where incremental advances are common, will have similarities to inventions described in the prior art, and the patent applicant must describe how their new invention teaches away from the prior art.
 - There is a one-year grace period in the United States, meaning that a U.S. patent application can still be filed within one year of the initial public disclosure of the invention. However, no such grace period exists in most other countries in the world, including European countries. Once an invention has been publicly disclosed, the ability to patent it in most countries of the world is permanently lost.
 - With the recent passage of the America Invents Act (AIA), on March 16, 2013, the United States transitioned from a “first-to-invent” system for awarding a patent to a “first-inventor-to-file” system, which is more consistent with patent law in other countries. What this means to an inventor is that if you invent an invention, and another inventor independently develops the same invention and files a patent application claiming the invention prior to your patent filing date, then the other inventor stands to be awarded the patent.

Recent Supreme Court Cases Impacting Patent-Eligible Subject Matter

- **Mayo v. Prometheus:** This case revolved around the measurement of a known metabolite and use of the measurement to determine therapeutic efficacy of a compound. The claimed invention was ruled as being ineligible for a patent because the claims involved interpretation of a known law of nature with no transformative step. The decision is controversial, and has had negative impacts on inventions consisting of claims drawn to diagnostic methods.
- **Association of Molecular Pathology v. Myriad Genetics:** This case involved a series of patents owned or controlled by Myriad Genetics with claims drawn to isolated DNA sequences, and methods to diagnose cancer by examining the sequences for mutations. The Supreme Court held that a naturally occurring DNA segment is not patentable merely because it has been isolated. The court held that artificially created cDNA molecules are patent eligible because they aren't naturally occurring.
- **The Bilski case:** This Supreme Court case involved claims directed to a method for hedging risk in commodities trading, but the implications of the court's decision go beyond the claimed method and state that in order to be patent eligible, the claim must be tied to a machine or apparatus, or must involve a transformative step that transforms a particular article into a different state or thing.
- **Collectively,** these three high-profile cases have had a chilling effect on patent claims drawn to diagnostic methods. In this era of increasingly personalized medicine and increasing use of diagnostic tests to direct treatment, there is concern that these cases may lead to decreased commercial investment in new diagnostic technologies and tests.
- **The invention must be non-obvious to a person having ordinary skill in the art.**
 - If an invention represents an obvious extension or derivative of an invention described in the prior art, it may not be patentable. The invention may face an obviousness rejection if the patent examiner can combine multiple prior art references with the assertion that a person with skill in the art would have been able to develop the same invention by combining the teaching of the prior art references.

- Obviousness rejections are very common in the patent prosecution process, particularly with regard to inventions in the biotech arena with its heavy concentration of prior art in the scientific and patent literature. However, obviousness rejections can be overcome if the patent applicant can demonstrate how the invention teaches away from the prior art, particularly if the invention is based on unexpected results that would not have been anticipated by a review of the relevant prior art. Obviousness rejections may also be overcome by technical arguments that describe why the teachings of the references in the combination are incompatible or cannot otherwise be combined.

■ **The invention must have a specific, substantial, and credible utility.**

- This requirement means that the invention must be applicable to some sort of industrial use. The utility requirement is typically not one that comes in to play during the patent prosecution process. If it were difficult to establish a specific, credible utility associated with an invention, we wouldn't elect to file a patent on it in the first place.

■ **The invention must be sufficiently described in the patent application.**

- **The invention must be enabled:** This requirement means that the invention must be sufficiently described in the specification of the patent application such that a person skilled in the art could make and use the invention based on the description without the need for undue experimentation. The enablement requirement is frequently used as justification by a patent examiner to reject claims in biotech-related patent applications filed by academic institutions in which the patent applicant is attempting to claim a therapeutic composition or method for use in treating a certain human disease, but the invention is lacking conclusive data from relevant animal model systems. The decision to file a patent application in the academic environment is often driven by a pending public disclosure, so we may have to file a patent application in order to avoid a potential loss of rights, but in ideal world, we might wish to wait to file the application until more enabling/supporting data can be developed.

During the examination process, the examiner will often assert that a skilled artisan would have to engage in undue experimentation

in order to determine how to practice the claimed invention, and the patent applicant must be able to provide data/evidence (linked to the description of the invention in the specification of the patent application) supporting the contention that the invention can be practiced as claimed. This process frequently results in amendments to the claims of the patent to adjust their scope to parameters that the examiner believes are enabled.

INVENTORSHIP ON A PATENT

- Inventorship is a legal determination, and differs from authorship on a scientific publication.

- **Inventorship on a patent is tied to the act of conception of the invention.** If a person did not contribute to the conception of the invention, they are not an inventor, even if they helped reduce the invention to practice.
- **There is no requirement for reduction to practice in order to be an inventor.** One can make an inventive contribution by contributing to the conception of the invention without being personally involved in carrying out the process of enabling the invention, provided that carrying out this process does not require additional inventive contribution. However, as stated in the section above, in order for a patent to actually issue, the invention must be sufficiently described in the patent to enable a skilled artisan to make and use it.
- **With regard to joint inventorship, if a person contributes to one claim on the patent application, they are an inventor,** and will be an inventor on any subsequent patent that issues that contains the claim to which they made an inventive contribution. Individuals may be joint inventors even if they did not physically work together or at the same time, and even if the type or amounts of their respective contributions to the invention are different. There is no requirement that an inventor make a contribution to every claim on the patent application to be listed as an inventor. An inventive contribution to a single claim is sufficient.
- **Differences between inventorship and authorship.** An individual working under the direction and supervision of a laboratory PI might well be listed as an author on a scientific publication containing data developed by the individual. Let's suppose this same work leads to the development of a patent application; unless this individual also made contributions to the

conception of at least one claim in the patent application, they should not be listed as an inventor.

Additionally, there is **no significance associated with the order in which inventors are listed on a patent application. An individual is either an inventor, or they are not.** This differs from typical practices around the listing of authors on a scientific publication, such that the individual(s) who did the lion's share of the work are listed first, and the laboratory PI is often listed last. This convention does not apply to the listing of inventors on a patent. There is no such thing as a "senior inventor", or a "junior inventor."

- **Who makes the inventorship determination? Why is it so important?** Because inventorship is a legal determination, this determination is made by outside patent legal counsel at the time that the patent application is being drafted. Verifying correct inventorship is important for insuring the enforceability of the ensuing patent. If the inventorship on a patent is incorrect, it can open the door for a third party to challenge the validity of the patent and potentially overturn it.

THE PATENT PROSECUTION PROCESS

- **Patent Prosecution is a Lengthy Process:** As a faculty inventor, prepare yourself for a long journey (**FIGURE 5**). The span of time from the date that a patent application is filed until the inventor receives an issued patent (if this happens) is a lengthy one and can encompass a range of years. Some cases can issue in 3-4 years after filing, while more complex cases can take 7-8 years (or more), before the patent is granted. It is very difficult to predict the pendency period when an application is filed. There are ongoing efforts at the United States Patent & Trademark Office to reduce the patent pendency period.
- **Patent Life:** The term of a patent is 20 years from the filing date of the earliest non-provisional U.S. application to which the patent claims priority.
- **Patent Legal Counsel:** Baylor College of Medicine works with outside law firms that have experience in patent drafting and prosecution. These firms are engaged by the BCM Office of General Counsel (OGC), often in consultation with BLG project

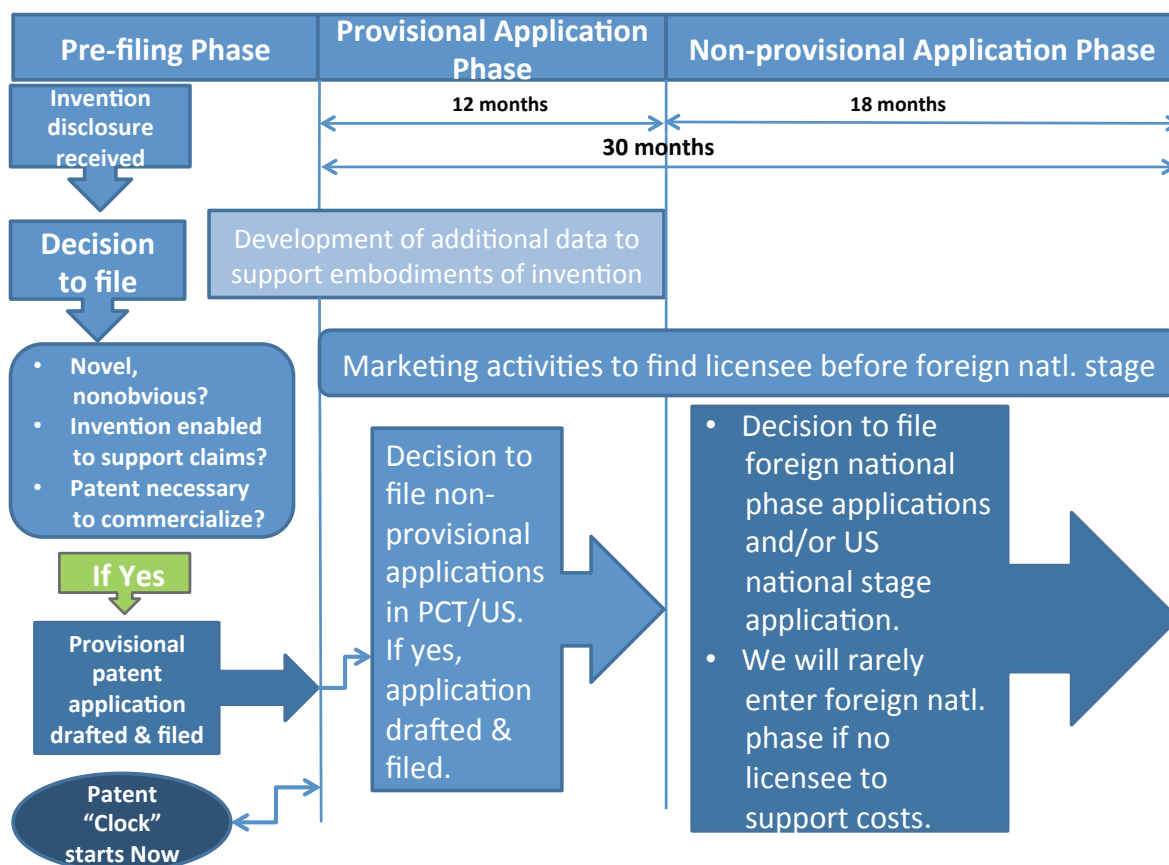


FIGURE 5: Patent Filing Process Summary

managers. Outside patent law firms are chosen based on the relevance of their technical expertise to the invention, the quality and value of their service, and their understanding of factors that impact university patenting decisions and strategy. Most outside patent counsel who are engaged by the college have dual backgrounds in science and law (a combination of Ph.D. and J.D., for example). In addition to attorneys, law firms frequently employ Patent Agents (someone who is admitted to practice before the USPTO, but not an attorney) with strong technical backgrounds. Patent agents are often the “troops on the ground” and are frequently responsible for much of the drafting of a patent application, and they are often heavily involved in managing the patent examination process (acting under supervision of a more senior attorney).

- **Provisional Patent Applications:** The first step in the patent prosecution journey will almost always involve the preparation and filing of a provisional patent application. Provisional patent applications are not examined by a patent examiner, but they can be useful for establishing the priority date for an invention, to the degree that the invention is described in the provisional application. Like most academic institutions, our decision to file a provisional patent application is often driven by a pending public disclosure of the invention (meeting abstract, poster, or presentation; or a manuscript). Filing a provisional patent application can protect proprietary rights associated with an invention that would otherwise be lost through public disclosure. However, the scope of rights protected under the provisional application limited to the degree that the invention is described in the initial filing. Although a “cover sheet” provisional patent application can be filed as a last minute solution for urgent and unexpected situations, it is to the college’s strong advantage (and yours, as a faculty inventor) to file a more completely developed application that is facilitated by disclosure of the invention to BLG in plenty of time to craft a fleshed-out application.

Provisional patent applications must be converted to a non-provisional patent application within one year of the provisional filing date. Additional new data that have been developed during the intervening year can be added to the non-provisional application to more fully describe and support the parameters of the invention. Conversion of a provisional patent application to a non-provisional application is costly, so we will only convert a provisional application if it makes business sense, i.e., we have found or will very

likely find a licensee in the near future to pay for ongoing patent costs. If we’ve marketed the invention and received negative feedback from potential licensees, we may elect not to convert the application. Additionally, if data developed during the year between the provisional filing date and the conversion date fail to support the case for continued prosecution (experiments may have yielded negative or inconclusive data), we may elect not to convert a provisional application. The decision to convert is always driven by the degree to which the patent application may add value to the invention in a way that is necessary to secure a licensee.

- **Non-Provisional Applications:** When a decision is made to convert a provisional application, we will frequently elect to file a non-provisional PCT application. The acronym PCT stands for Patent Cooperation Treaty, which is a treaty that has been signed by over 140 member countries, including all major global economic leaders (countries where we might wish to file). Once we’ve prepared and filed a PCT application, this acts as a gateway to provide the patent applicant with the option to enter the national phase of patent prosecution in any PCT signatory country. The national phase entry deadline occurs eighteen (18) months after the conversion date. During this interim period, BLG will normally actively market the invention and seek to execute a license with a commercial partner prior to the national phase entry deadline. The costs associated with continued patent prosecution dramatically ramp up once the national phase of prosecution is initiated.

For inventions that had been publicly disclosed prior to filing a patent application, if we convert to a non-provisional application, we will continue prosecution in the U.S. alone.

- **The National Phase Entry Decision:** The national phase entry decision must be made within 18 months of the PCT application filing date; or 30 months from the initial provisional filing date. At the national phase entry point (actually, a couple of months before the deadline) we will instruct our patent counsel to enter countries where we desire to continue patent prosecution. Entry into foreign countries requires a very substantial investment, and for this reason the college seldom elects to continue foreign patent prosecution into the national phase, unless we have a licensee supporting patent prosecution costs. National stage filing and prosecution in a limited set of countries (U.S., Europe (via the European Patent Office), Canada, Australia, Japan, and potentially

China and India) will easily top \$150,000 or more. In addition to fees and annuities, translation costs are big driver of foreign patent filing costs. For these cost-driven reasons, we aim to have a licensee in place to support foreign filing and prosecution costs in advance of the national phase deadline. If we're approaching this deadline without a licensee in place, decisions will have to be made regarding the scope of continued prosecution.

- **The Patent Examination Process:** Once the decision has been made to prepare and file non-provisional application and continue prosecution, the application will be examined by a patent examiner. The examination process is lengthy—we may not expect to see an Office Action from the patent examiner for two years or more from the conversion date. The examination process, and our odds of successfully obtaining an issued patent, can be impacted by several factors:

- i. The prior art that is relevant to the invention (including the inventor's own previously published works). If the invention resides in a "hot" area of scientific study, it is likely that multiple citations from the art will be used by the examiner to assert that the invention is not novel, or that it is anticipated by the existing art.
- ii. The skill and expertise of the patent examiner—this is a factor over which the applicant has no control. Some examiners will exhibit a good grasp of the elements of the invention, while others may require considerable effort on the part of the applicant to educate the examiner regarding the features of the invention and how it differs from the prior art, etc.
- iii. The willingness of the faculty inventor to be actively engaged in the process and work productively with outside patent counsel. The amount of time that a faculty member might be expected to commit to the patent prosecution process will vary with the complexity of the case and the types of objections raised by the patent examiner. An engaged inventor is always a strong asset in the quest to obtain an issued patent with claims that will appeal to a commercial licensee.

During the examination process, the patent applicant can expect to have their claims denied by the patent examiner. The process of patent examination really boils down to a negotiation between the applicant and the examiner to determine the scope of the claims of the eventual issued patent. Faculty inventors can expect to work with outside patent counsel to craft responses to the examiner in our effort to get claims to

issue. The outside patent counsel that the college engages will have technical expertise that is relevant to your invention, but as the inventor, your depth of knowledge and expertise related to the invention and your field of study will be essential to secure a successful outcome.

- **Restriction Requirements & Office Actions:** The first communication that we can expect to receive from the patent examiner (an "Office Action") will most often be a Restriction Requirement. The patent examiner will review the claims of the patent application, and if he/she believes that the claims represent more than one distinct invention (a pharmaceutical composition vs. a method of using it, for example), the examiner will divide the claims into distinct groups (the process of restriction). The patent applicant must then choose a single claim group to pursue through continued prosecution. The remaining claim groups may also be prosecuted at a later date in separate patent applications called divisional applications.

The applicant's response to the Restriction Requirement will be followed by a series of Office Actions, during which the patent applicant can generally expect to have their claims denied by the patent examiner. Claims may be rejected on the basis of obviousness, lack of enablement, lack of novelty, or for other reasons. Our experience with prosecuting patents in the biomedical sphere is that claim rejections based on obviousness and/or lack of enablement are very common. Our outside patent counsel, working in collaboration with the faculty inventor, will prepare a response to the Office Action. The response to the Office Action will state the reasons why we believe the examiner's objections to our claims should be overcome and a patent should be granted. This process will often involve amendments to the claims of the application (typically narrowing their scope) to address the examiner's concerns and to craft the claims into a form that the examiner will allow to issue. The examination process is, at its core, a negotiation between the examiner and the applicant. Not every patent application will result in an issued patent. There are cases in which the process by which the claims are amended to place them in a position where they will be allowed by the examiner results in claims that are so narrow in scope that they are of minimal value to a licensee.

- **Notice of Allowance and Issuance:** If the examination process results in a determination by the examiner that the claims are allowable, the examiner will issue a Notice of Allowance. The applicant must then pay a patent issuance fee for the patent to be granted. If the applicant wishes to prosecute any divisional

THE LEAHY-SMITH AMERICA INVENTS ACT “AIA”

On September 16, 2011, the Leahy-Smith America Invents Act (“AIA”) was signed in to law by President Obama. The major thrust of this patent reform legislation was to more closely harmonize U.S. patent law with that of the rest of the world. Key changes associated the AIA include:

- **Transition from a “first to invent” system to a “first-inventor-to-file” system.** This change went into effect on March 16, 2013, and gives priority for granting a patent to the first inventor to file a patent application. This means that the determination of whether an invention is novel or non-obvious will be based on the prior art that existed on the date that the patent application was filed, and not on the date that the invention was actually conceived. Inventors still have a one-year grace period during which the inventor’s own public disclosures or the disclosures of third parties who obtained their information from the inventor may not be used as prior art if the disclosures occurred within 12 months of the filing date of the patent application.
- **New post grant review procedures:** Post grant review means that a person who is not the patent owner may request that the USPTO examine the validity of an issued patent within 9 months of the date of issuance, but this change impacts patents filed under the new “first-inventor-to-file” system. Assertions of patent invalidity may be based on grounds of lack of novelty, obviousness, insufficient written description of the invention, or lack of enablement. These proceedings will be administered by the Patent Trial and Appeal Board.
- **Will the AIA change patenting practices at BCM?** The AIA will not significantly change our patenting practices. There is little advantage to be gained by filing a provisional patent application earlier, particularly if the claims of the patent application are not sufficiently enabled by the written description of the invention in the specification of the patent. Nothing is gained by filing an insufficiently enabled patent application. As is often the case in the academic environment, a pending public disclosure of an invention will often trigger the decision to file a patent application. But, the potential to receive patent claims that will add value to the invention and potentially enable us to land a commercial partner will always be the crucial factor in the decision to file.



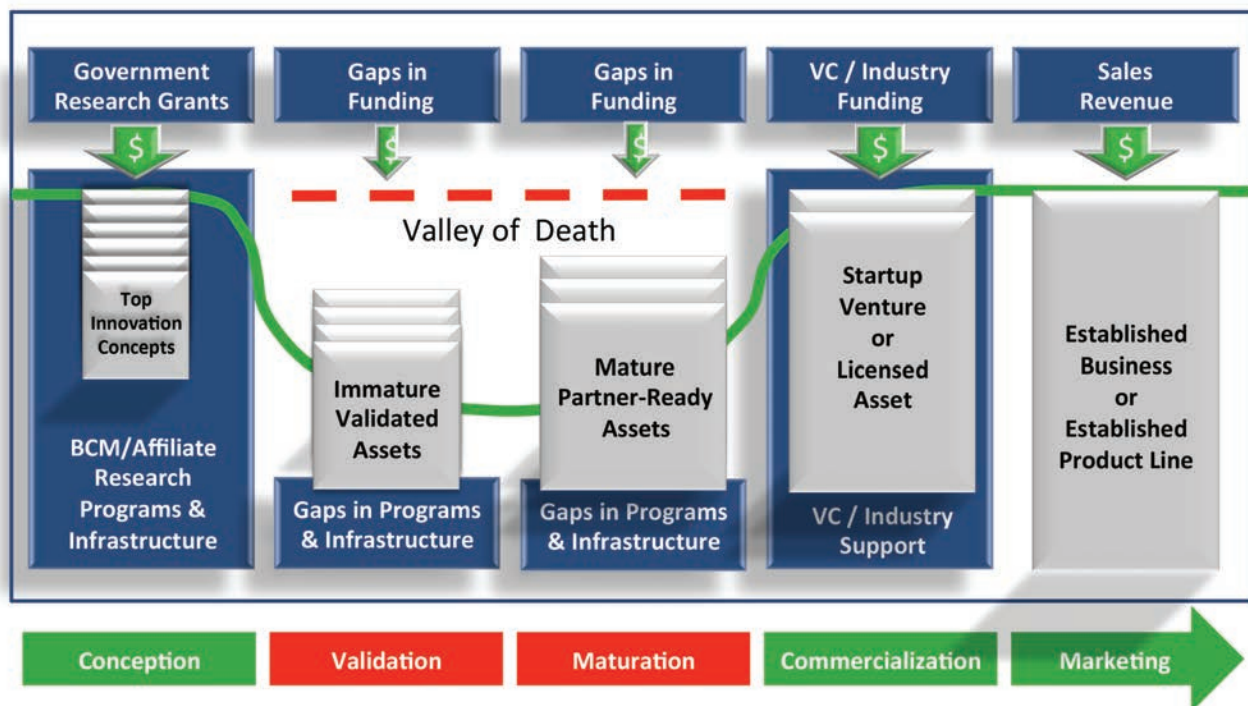


FIGURE 6: Innovation is Currently Limited by Gaps in Support for Asset Development

applications, this process must begin prior to issuance of the parent application.

INNOVATION DEVELOPMENT: Baylor College of Medicine Innovation Development Center

Challenge Addressed: The Innovation Development Center (IDC) is a new service unit at Baylor College of Medicine that was created to address the gap in support for early-stage biomedical asset development commonly referred to as the “Valley of Death” (FIGURE 6).

- The IDC Asset Development Model:** The gap in support for biomedical innovation exists at the boundary between academia and industry and is not the “sweet spot” for either. Biomedical product development projects are no longer eligible for basic research grants. Unfortunately, in the early stages they are not yet investable opportunities for industry either. To try and fill this void many new programs have been created by state, federal, and regional government, philanthropists etc. In most cases no single organization will be in the position to support the commercialization of an early-stage biomedical asset alone. However, in many instances it is possible to move a biomedical asset through the difficult preclinical stage of development utilizing a diverse combination of resources and expertise. The IDC Asset Development Model utilizes this approach to efficiently develop BCM’s top innovation concepts into mature biomedical

assets that are ready for commercialization (FIGURE 7).

- The Asset Development Process:** Implementation of this approach involves completion of the asset development process outlined below (FIGURE 8).
- Identification of Candidate Assets:** A majority of BCM’s innovation concepts are disclosed and subsequently evaluated by BLG. However, many early-stage innovations are not yet ready to be patented or lack a clear route to commercialization and are thus not disclosed. A prime example is the discovery of potentially important drug targets prior to discovery of patentable drug candidate molecules. Without adequate support these inventions and discoveries may never progress beyond promising concepts. In absence of another mechanism to bring them to light, BCM would be unable to effectively fulfill its translational mandate. For this reason IDC proactively solicits new innovation concepts through one-on-one discussions with faculty and through the administration of programs such as the Innovation Development Center Pilot Project Award program (formerly the Alkek Award for Pilot Projects in Experimental Therapeutics).
- Selection of Top Innovation Concepts:** IDC provides a higher level of service and investment for those BCM innovation concepts which demonstrate the highest potential for success. The IDC Asset Development Model serves as a guiding

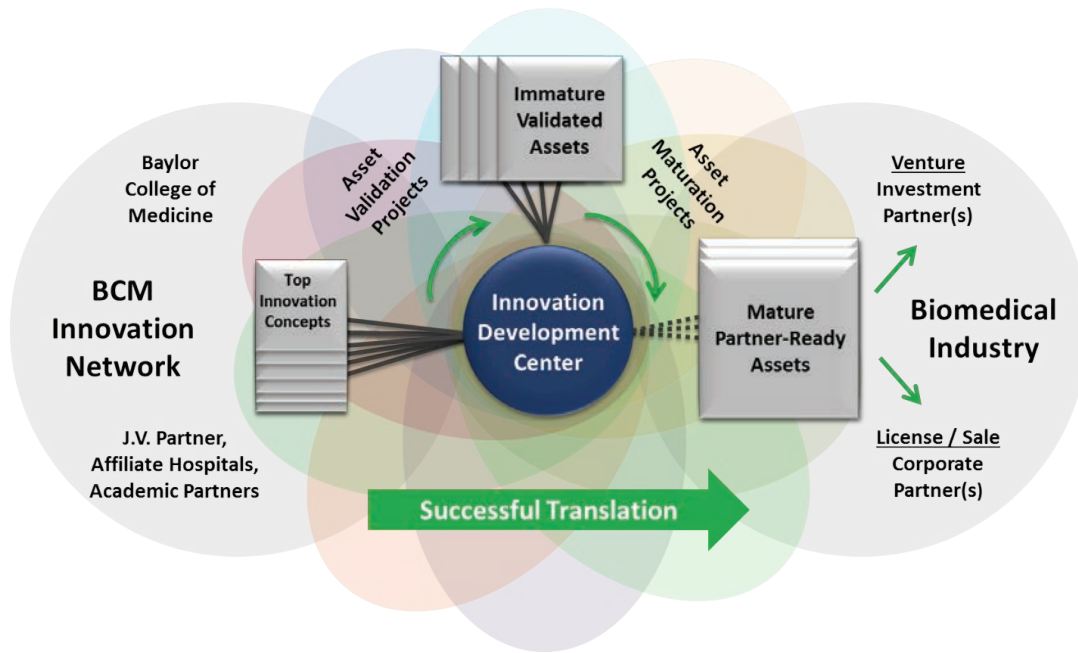


FIGURE 7: IDC Asset Development Model

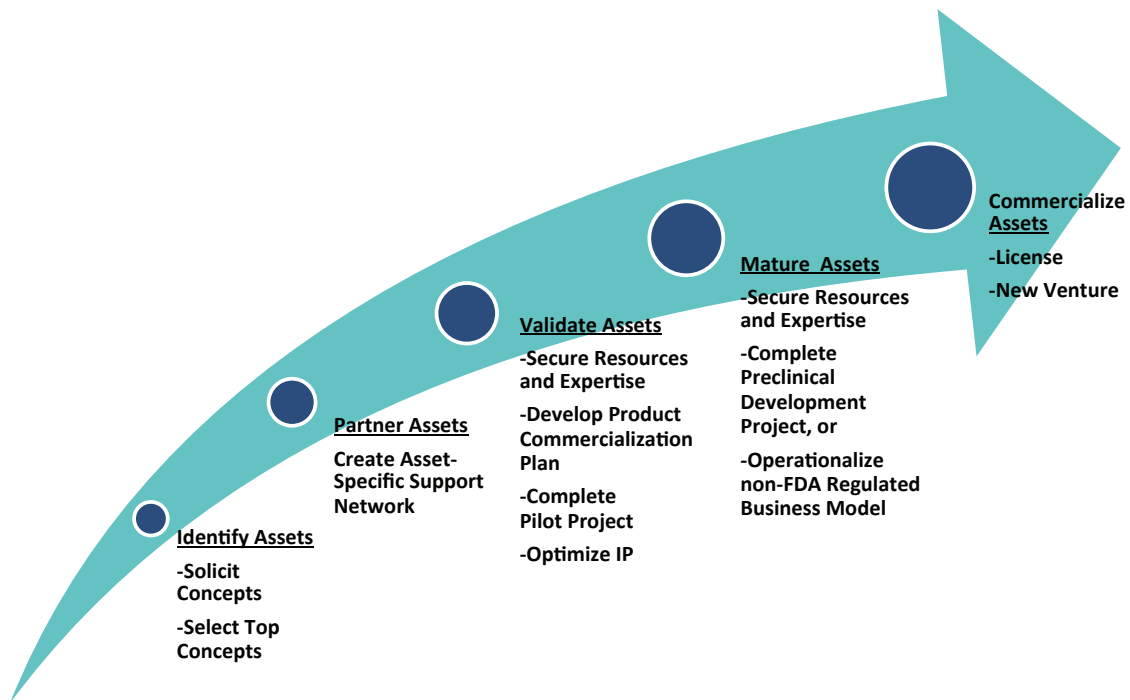


FIGURE 8: IDC Asset Development Process

template for organizing the process to select BCM's best technology assets and develop plans to add value to and de-risk those assets so that they can be successfully commercialized (**FIGURE 9**). Even when BCM successfully licenses a new therapeutic or device technology to a commercial partner, the odds of that technology ever becoming a product on the market depend on a number of factors and are hence difficult to predict. In most cases, the technologies that we license represent research discoveries that hold great promise, but also carry great risk and require years of development and investment by the licensee before they'll ever be sold commercially. The rationale behind the asset development process is to "shift the curve" and increase the probability of success by adding value to a select group of technologies in an informed manner that leverages multiple sources of expertise, both internal and external to the college.

■ Steps in the Asset Development Process

- **STEP 1. Asset Selection:** The process of selecting the top innovation concepts that will enter the asset development program:
 - The asset represents an **impactful potential solution for an important unmet societal need**;
 - The asset represents a **technically feasible development project**, such that a targeted investment will be capable of moving the asset to a meaningful value inflection point and enhance the odds of commercial success;

- The asset is **proprietary** – it has novel, non-obvious characteristics that suggest a real possibility to obtain commercially valuable patent claims.
- The asset has significant **commercial potential** – representing both a commercial solution that customers will be willing to pay for and an attractive return to the investors who fund commercial development.

- STEP 2. Creation of Asset-Specific Support

Network: As described earlier, efficient asset development is facilitated by utilizing a diverse team of partners with complementary resources and expertise. IDC assists investigators to assemble a team of both internal and external partners to implement their product commercialization plans. **Figure 10** illustrates the IDC Support Framework, a conceptual framework for identifying and recruiting complementary partners to assist in development of specific biomedical assets. As described below, these partnerships will be utilized iteratively to facilitate the progression of assets through the asset development process.

- STEP 3. Asset Validation

■ Secure Resources and Expertise

Resources: Funding for the validation phase can be obtained from sources that are appropriate for funding proof-of-concept research, including the Innovation Development Center Pilot Project Awards

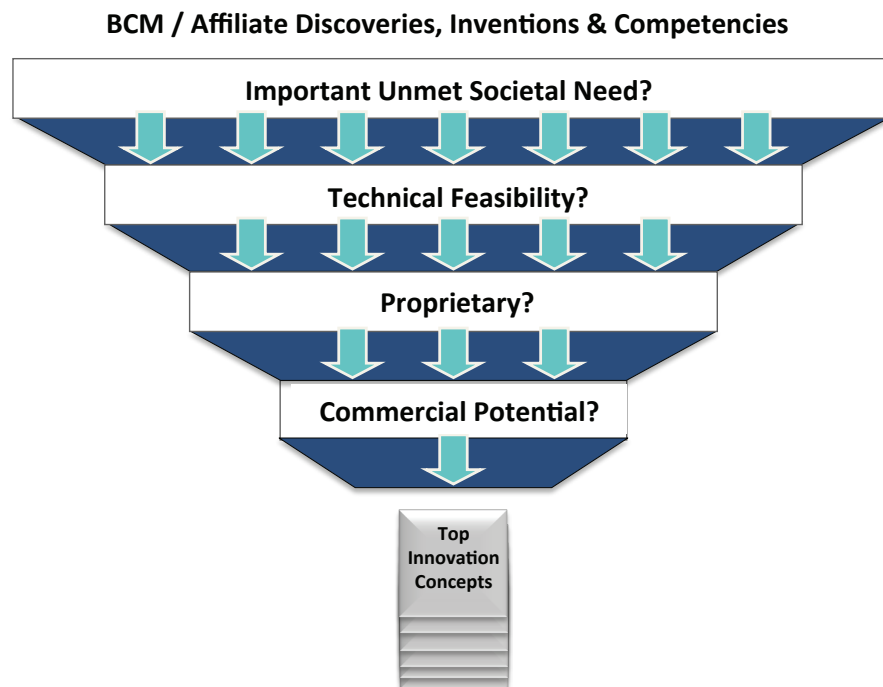


FIGURE 9: Selection of Top Innovation Concepts

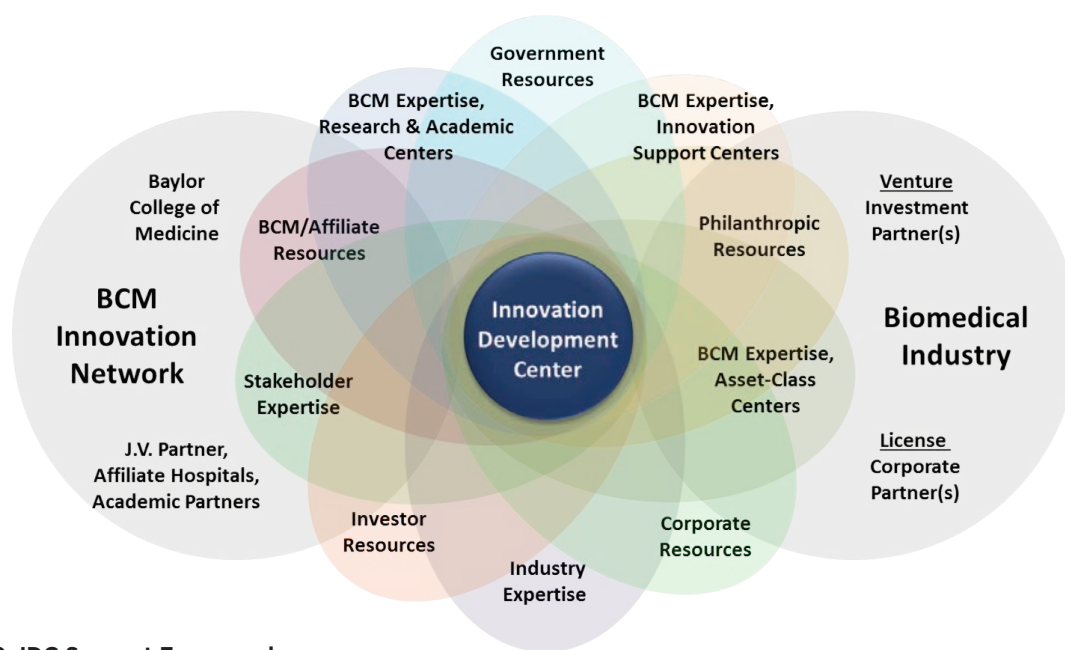


FIGURE 10: IDC Support Framework

administered by IDC, NIH Small Business Technology Transfer & Research (STTR) grants, CPRIT “Bridging the Gap” Early Translational Awards, corporate research sponsorship, and philanthropic funding. IDC will work with BCM’s Office of Philanthropy and Alumni Relations to increase overall philanthropic support for asset development. The IDC team will work with faculty members to identify and leverage the best sources of funding to advance their particular project.

- **Expertise:** During this phase it is important to begin bringing together a group of experts that guide the asset through the development process in the most efficient manner. The first step is generally the retention of a professional consultant with the expertise to spearhead creation of an actionable product commercialization plan. Using this plan, IDC and the faculty member will recruit partners with the expertise required to facilitate asset validation.

■ **Creating Actionable Product Commercialization Plan:**

This plan details the preclinical development work that must be done to support clinical entry. It will frequently involve the recruitment of outside consultants and subject matter experts from industry to develop the road map for transitioning the asset from the laboratory bench to the clinic. This road map includes: 1) identification of the most attractive indications and market sectors to target, 2) a “target product profile” which describes the precise characteristics that the product should have in order to be successful, and 3) the preclinical/early-stage product development

plan describing steps necessary to create the product and gain regulatory approvals. The goal of the plan is to lay out the most efficient path to successful commercialization and clinical entry.

- **Complete Pilot Project:** This involves performing the identified preclinical proof-of-concept experiments/demonstrations and analyzing the data.
- **Secure Optimal Intellectual Property Protection:** This may mean filing new patent applications to cover new aspects of the invention needed to insure exclusivity and viability for our eventual commercial partner. This step will involve working with outside consultants and outside patent counsel, and will frequently require input from the faculty inventor.

- **STEP 4. Asset Maturation**

■ **Securing Resources and Expertise**

- **Resources:** IDC assists faculty in their pursuit of funding for asset maturation. Sources of funding for asset maturation include phase II STTR/SBIR grants, Texas Emerging Technology Fund grants, CPRIT New Company Product Development awards, and corporate or investor-sponsored research. It is frequently necessary to create a development company (Devco) to take advantages of these funding sources. Devcos are created to facilitate the development of products to a point where they can attract commercial partners. IDC also works to attract commercial investors to invest in these development projects through its newly created Impact Investments Program.

- **Expertise**
 - **Creating a virtual management team** for the development company. Such a team might include IDC staff, and/or outside consultants with appropriate backgrounds/skills for the project.
 - **Implementing the maturation phase** of the product commercialization plan. This generally corresponds to preclinical development for biomedical assets but can also, for example, involve the operationalization of biomedical services.

- **STEP 5. Asset Commercialization**

- **Developing a marketing package** to pitch the asset and associated data to potential commercial partners. Packaging and preparation for commercialization begins during the Asset Validation and Maturation phases and only culminates with the execution of a commercialization transaction as outlined below. Decisions about when to actively market and seek a commercial partner are based on parameters specific to the individual technology asset.
- **Executing a license/option agreement** with a commercial partner for rights to commercialize the asset. The agreement will be executed through the Baylor Licensing Group with either an established corporate development partner or a new start-up company venture.
- **Executing agreements with investors** in the case of a start-up company that is receiving outside investment. The execution of these activities will be coordinated by BCM Technologies, Inc., the college's wholly-owned venture development subsidiary. Not all assets that reach the commercialization stage will receive investment from an angel or venture investor—this is a very difficult outcome to predict.

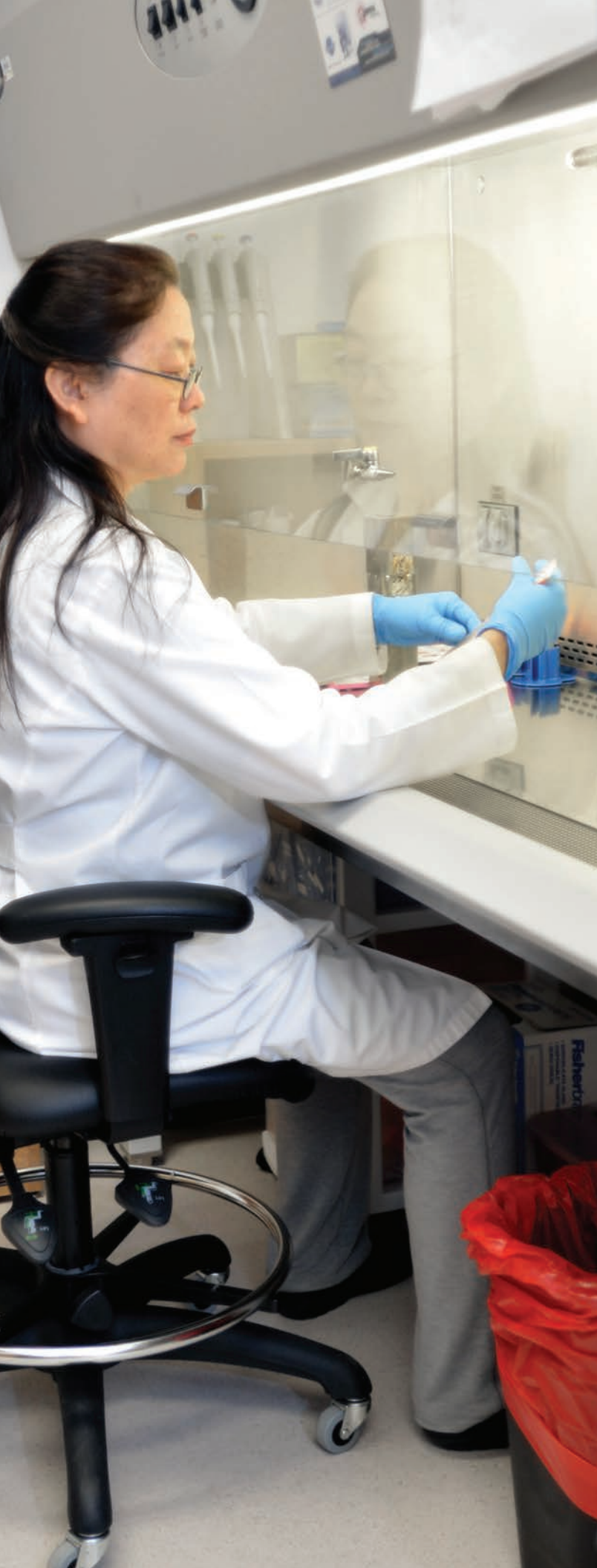
It All Takes Money: Sources of Asset Development Capital

- **The Innovation Development Center Pilot Project Awards Program:** This is an internal BCM fund administered by IDC to support proof-of-concept work around promising biomedical innovations with translational potential. There is a two-step review process associated with this proof-of-concept fund:
 - Scientific merit ranking consistent with the NIH scoring system.
 - Commercialization ranking based on intellectual property and commercial potential.

The award amount for an asset funded under this mechanism is typically \$100K, which is designed to fund a proof-of-concept research program

that will typically span a year in duration. Successful applicants will be required to provide progress reports to demonstrate the outcome of the funded work.

- **The NIH STTR/SBIR Program** (<http://sbir.gov/>): The STTR/SBIR program is a federal grant program designed to foster the growth and development of small businesses that focus on high tech products and services. The IDC team offers support services to assist BCM PIs who are interested in pursuing federal commercialization grant funding.
 - **Requirement for a company to be the applicant for this funding:** In order to pursue funding under this federal program, a company must be formed and the company will be the applicant for funding. The newly-formed company will then have an opportunity to pursue non-dilutive sources of commercialization grant funding to develop and de-risk the technology asset to improve the odds for commercial success.
 - **The Small Business Technology Transfer (STTR) Program** is an ideal funding source because it is specifically designed to support the transition of discoveries from the academia to industry, and actually requires the company to collaborate with an academic research institution.
 - **Company eligibility requirements:**
 - For-profit small business entity located in the United States (less than 500 employees).
 - The business must be majority-owned by (51% or more) by individuals who are U.S. citizens.
 - The company is the applicant for funding, not the academic institution.
 - **Who actually does the work under an STTR-funded project?**
 - Under the STTR program, there is a requirement that the small business partner with a non-profit academic research institution, making the STTR program the perfect vehicle to fund the early stage commercial development of a promising technology.
 - The **small business must perform at least 40 percent** of the work.
 - The **partnering academic institution must perform at least 30%** of the work.
 - The remaining 30% of the work can be performed by the company, the academic institution, or other third parties.
 - The company will enter into a subcontract with the academic



institution to govern the terms and conditions of the portion of work to be conducted at the research institution.

– **Who can serve as Principal Investigator?**

- For the **STTR** program, the **PI can have their primary appointment with an academic institution**, and they must be able to devote 10% of their time to the STTR-funded project.
- For the **SBIR** program, the **PI must be employed at least 51% of the time at the small business** entity.
- Because of the requirements associated with the appointment and time commitments of the Principal Investigator, the STTR program offers the best option for pursuing commercialization grant funding for most early-stage technologies.

– **What are the funding levels?**

- **Phase I** typically provides \$100-\$150K to conduct commercial proof-of-concept experiments over 6-month/1 year project duration.
- **Phase II** typically provides \$750K-\$1M for two additional years of research & development along the path to market introduction and commercialization.

■ **State Commercialization Grant Programs**

- **Cancer Prevention & Research Institute of Texas (CPRIT):** <http://www.cprit.state.tx.us/funding-opportunities/>

- **“Bridging the Gap” Early Translational Science Awards:** This mechanism provides funding for preclinical proof-of-concept research needed to move promising approaches along the path to clinical entry. There is no requirement for a company to be formed to apply for this funding.

- **New Company Product Development Awards:** Once a company has been formed, it can seek funding via this mechanism to support the development of new products for the diagnosis and treatment of cancer. The applicant company's operations must be located in the State of Texas.

- **Emerging Technology Fund:** <http://governor.state.tx.us/ecodev/etf>

- The ETF provides funding for small companies to develop and commercialize new technologies in a wide variety of technology

sectors. Applicant companies go through a multistep review process that begins at their local Regional Center for Innovation and Commercialization (RCIC). The RCIC for our region of the state is located at the Houston Technology Center. Companies that seek ETF funding must have a well-developed business plan, so this is not an appropriate funding mechanism for a newly-formed company at its infancy. The continued availability of ETF funding is dependent upon the political climate in Austin, and it could change.

■ **Ownership of the company: Transition from early grant funding stage to full-fledged commercial entity.**

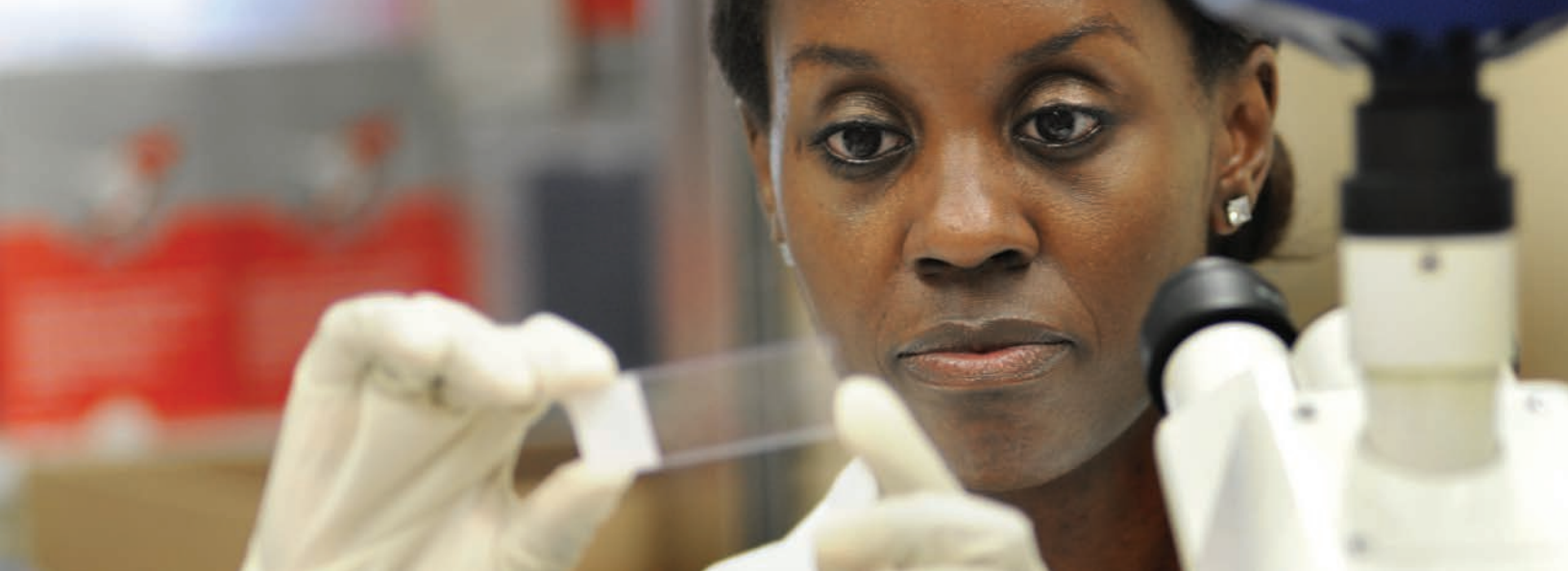
Founding PIs must understand that **control of the company will change** as the small company grows and its capabilities expand. When the company grows to become a successful commercial enterprise and is a candidate to receive outside investment, the founding PI should fully expect control of the company to shift to management personnel with depth of expertise in growing successful businesses in the biomedical sector. This transition should be viewed as a positive event by the founding scientist(s). In some cases, PIs want to retain control of the commercial development of their technology, and this is understandable because the technology that forms the basis for the company often represents the culmination of years of the PI's research program. But, in order to be successful, the company must have the

flexibility to make decisions that are in the best commercial interests of the business enterprise and the technology.

At the time the company is initially formed, it does not have a license to the technology/intellectual property owned by the college. The license agreement will come later, as the company obtains funding and resources necessary to successfully commercialize the intellectual property. The college does not want to license BCM-owned intellectual property to a commercial enterprise until it can demonstrate that it has the resources to develop the IP. The initial intellectual property agreement between the company and the college will (in most cases) be an exclusive option agreement.

An exclusive option agreement gives the company the right to exercise an option to negotiate and execute an exclusive license agreement, provided that the company achieves certain diligence milestones during the option period. Signing an exclusive option agreement provides the company with the ability to credibly represent to potential investors that they have a path to an exclusive license to acquire rights to the intellectual property that will form the technology basis for the company. At the same time, the option agreement format protects the interests of the licensor because the company will be required to successfully execute on diligence milestones before it can exercise its option. In the event that the company fails to deliver, the licensor (BCM) can potentially license those rights to a third





party at a later time. During the option period, BCM will refrain from offering license rights to the technology to any third parties. Typical diligence milestones to be achieved during the option period might include:

- Securing a specified amount of funding to develop the technology;
- Development of a business plan/product development plan to provide a roadmap for commercial development of the technology; and
- Hiring of management personnel.

■ **College Support of Newly Formed Small**

Businesses: As a faculty member who is involved with the process of founding a company, it is important to emphasize that you are not on the “commercialization battlefield” alone. The college offers multiple routes by which it may support your efforts and add value to the business entity. Not every newly-formed company can expect to receive support from the college— the ability of the college to provide supporting services and resources is limited, and it is influenced by college priorities. However, one of BCM’s strategic goals is to grow its commercialization outcomes and successes, and providing help to new start-ups is a route to accomplish that goal. The college may choose to provide support to start-ups in the following ways:

- **Corporate entity formation:** The act of forming a company requires the engagement of legal counsel and the preparation of filing of corporate documents. This process typically costs ~\$2,000.
- **Preparation of a product commercialization plan:** For certain projects, the college may choose to engage outside consultants/subject matter experts with appropriate industry backgrounds to develop a roadmap for moving the science toward clinical entry and commercial success. The individuals who will be engaged to do this activity on behalf of the college will bring

real world industry experience and track records to the table. The level of investment required to engage an industry consultant to produce such a plan is variable, but will be in the range of \$5K-\$10K, depending on how extensive the plan will be.

- **Patent prosecution support:** During the commercialization grant incubation phase, there will be ongoing patent costs that must be supported if the value of the underlying intellectual property is to be maintained. The level of investment that this activity may require is variable, but could range from \$10K-\$20K (preparation of a fully-developed utility patent application) to \$50-\$100K or more (if a decision to support foreign patent filing and prosecution is made; but this will be rare). Decisions around the level of patent cost support provided by the college will be made on a case-by-case basis, factoring in the needs of the company, the technology, and the college. Once a start-up company executes an option and/or license agreement with the college, the company will be expected to support ongoing patent prosecution costs.
- **Commercialization grant writing/editing expertise:** The use of internal and external commercialization grant writing expertise may be employed if warranted. The costs associated with this activity will vary with the level of engagement required.
- **Recruitment of clinical expertise at the college:** BCM clinical faculty may be recruited to provide input on the feasibility of clinical development, preferred patient populations, and issues related to clinical adoption of the technology.

■ **Responsibilities and Expectations of the Faculty**

Founder: The act of forming a company and committing to pursue commercialization grant funding is not a trivial undertaking. The faculty founder can expect to dedicate considerable

time to this process. It is important for the faculty member to understand the purpose behind commercialization grant funding. Commercialization grants are designed to help small businesses develop innovative solutions into products. They should not be viewed as another mechanism to support a faculty member's basic research program.

As a faculty founder, you will have help during the commercialization process, but you must be willing to be the "champion" for your technology. Serving in this capacity will require commitment from you in the following areas:

- **Substantial contribution to the commercialization grant writing process:** You are the resident expert with regard to your technology and your field of study. You will contribute to the commercialization grant writing process in the following areas:
 - A description of the technical background and the problem/unmet need that your technology solution proposes to address.
 - A description of relevant preliminary data.
 - Development of specific aims to be achieved under grant funding.
- **Active supervision and/or involvement in the project** if it is successfully funded.
- **Participation in meetings** with potential commercial partners/investors.
- **Consultation with external experts** to assist in the development of product commercialization plans, as applicable.

PARTNERING INITIATIVES: BUILDING RELATIONSHIPS

Partnering meetings with companies and/or investors may be coordinated by Andrew Wooten and/or BLG project managers working together. These meetings may involve biotech or pharmaceutical companies, medical device companies, early stage venture investors, entrepreneurs, or other individuals or groups interested in partnering with BCM. The commercial partner may have a very specific need or interest that they wish to discuss, or they may be interested in building a relationship with key BCM faculty thought and opinion leaders. In most cases, the ***development of a personal relationship significantly precedes any formal business relationship***, usually by a matter of months or years.

Prior to the meeting, background information will be gathered from the potential partner to be sure that the meeting matches the needs of the partner with

faculty who represent a "fit" with the partner's profile. Most partnering meetings will be targeted, strategic discussions with faculty who have research programs that align strongly with the partner's interest. Faculty involved in these meetings will receive guidance on the type/scope of material that the partner is most interested in learning about. With many introductory meetings, the focus will be less on an in-depth presentation and analysis of scientific data, and may instead focus on a broader overview of the faculty member's research program with an emphasis on a few select pieces of data. The person representing the industry partner may or may not have scientific background, so it is important that the presentation be tailored to meet the needs of the audience.

- BCM's research expertise and capabilities are actively promoted to potential industry partners. There are additional online tools that faculty can use to promote their collaborative research interests. These tools include:
 - The BCM Signature software application, which allows users to build specialized, targeted online profiles around specific interests: <https://www.bcm.edu/signature>
 - Virtually Integrated Institutions for Clinical and Translational Research (VIICTR) has tools to allow faculty to add information to their profiles: <https://viictr.org/>
- Should you receive inquiries from an industry scientist, business development professional or investor, please be sure to inform your BLG Project Manager, so that they can follow up and coordinate any follow-on activities. It is important to be mindful of disclosing any confidential, unpublished data prior to signing a confidential disclosure agreement (CDA). A premature disclosure may negatively impact patentability of the disclosed data or information.

CONCLUDING REMARKS

The developers of this guide sincerely hope that the content helps to clarify and demystify the technology commercialization process, which is complex. No single guide can explain all of the different situations, contingencies, and variables that may be encountered along the commercialization path, but our intent has been to provide you with an overview of the process so that as a faculty member you can enter it from a more informed vantage point. There are many issues around start-up company management, operations, funding, and strategy that aren't covered here, and warrant a separate guide all their own.

CONTACT INFORMATION

Baylor Licensing Group

Phone: 713.798.6821
General E-mail: blg@bcm.edu
Disclosure submission link:
<https://ota.vpdr.bcm.tmc.edu/disclosuredefault.asp>
BLG website: <https://www.bcm.edu/research/office-of-research/baylor-licensing-group/>
Director: Michael B. Dilling, Ph.D., CLP
E-mail: michael.dilling@bcm.edu
Physical location: BLG offices are located on 6th floor of the Jewish Wing

Innovation Development Center

Phone: 713.798.2116
Executive Director: Andrew Wooten, M.S., M.T.M
E-mail: andrew.wooten@bcm.edu
Physical location: Dan L. Duncan Institute for Clinical & Translational Research (ICTR), on the 1st floor of the Jewish Wing.

BCM Technologies, Inc.

Phone: 713.795.0105
President: Caroline Popper, M.D.
E-mail: popper@popperandco.com
Physical location: 2 Greenway Plaza, Suite 910, Houston TX 77046





SterilGARD II

THE BAKER COMPANY

CAUTION
THIS HOOD SHOULD NOT BE USED
WITH THE VIEW SCREEN OPEN
ABOVE THE 8 INCH OPENING MARK.

Baylor
College of
Medicine

