



TEXASTECH INNOVATION ECOSYSTEM Commercialization Roadmap





TEXASTECH UNIVERSITY

THE COMMERCIALIZATION ROADMAP

A comprehensive document created to support the success of innovators and entrepreneurs at Texas Tech.

Innovation Assessment

1. Do you have an innovation?

- A. D Yes, I have a working prototype.
- B. D Yes, I have a prototype drawing.
- C. \Box No, I have a concept or would like to contribute to a team.

2. Do you have intellectual property?

- A. 🛛 Yes, I have an issued trademark, copyright, or patent.
- B. 🛛 Yes, I have disclosed technology.

3. Do you have a team?

- A. 🔲 Yes, I have a fully established team (i.e., C-suite established).
- B. 🛛 Yes, my team is partially defined.
- C. D No, I do not have a team established.

4. Do you have scientific research to support your idea?

- A. 🗆 Yes, I have published research.
- B. 🔲 Yes, I have research, but it is unpublished or in process.
- C. D No, I do not have scientific research.

5. Have you legally established your business?

- A.
 Yes, I have established a legal business entity.
- C. \Box No, I do not have an established legal business entity.

6. Do you have a business plan?

- A. 🛛 Yes, already vetted by industry professionals.
- B. 🛛 Yes, needs vetting by industry professionals.
- C. 🛛 No, I do not have a business plan.

7. Have you received any grant funding?*

- A. 🔲 Yes, I have received federal grant funding (e.g., NIH, NSF, or STTR/SBIR).
- B. 🛛 Yes, I have received state funding.
- C. 🔲 No, I have not received any grant funding.

*If you answered "yes" to this question, contact the Innovation Hub at innovationhub@ttu.edu. or the Office of Research Commercialization at patents@ttu.edu.

8. Do you have investors?

- B. 🔲 Yes, private investors (e.g., personal, family, and friends).
- C. D No, I do not have investors.

9. Are you TTUS faculty, staff, or student?

- A. Yes, I am a TTUS faculty, staff, or student, and my ideas are related to my role in the university system.
- B. Yes, I am a TTUS faculty, staff, or student, and my ideas are not related to my role in the university system.
- C. D No, I am not affiliated with TTUS.

10. Do you have prior startup experience?

- A. 🛛 Yes, I have been a prior startup founder.
- B. 🔲 Yes, I have been involved with a startup in some capacity.
- C. D No, I do not have prior startup experience.

Add up your points using the key below:

TOTAL POINTS:

A=3 Points	0-14 Stage 1: Ideation
B=2 Points	15-24 Stage 2: Commercialization
C =1 Point	25-30 Stage 3: Acceleration

Acknowledgments

The Commercialization Roadmap was an enormous undertaking by faculty, staff, and leadership of the TTU Office of Research and Innovation. Thank you to the Innovation Hub team: Kimberly Gramm, Associate VP of Innovation and Entrepreneurship, who led the effort with the support of Taysha Williams, Program Director. Our hope is that the Innovation Ecosystem continues to flourish in West Texas with the guidance provided in this resource tool.

A special thanks to the Penn Center for Innovation (PCI) team for providing insights on the development of PCI's Commercialization Guide. Their support was invaluable in the development of Texas Tech's Commercialization Roadmap. We are grateful to the PCI team for their permission to use their materials to guide our process. We also acknowledge the time and effort of the ORC leadership team and TTU Office of General Counsel in reviewing this resource.

References

https://pci.upenn.edu/help/commercializationguide

https://www.uspto.gov

https://www.sbir.gov

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"What do you need to start a business? Three simple things: know your product better than anyone. Know your customer, and have a burning desire to succeed."

- Dave Thomas

O How Do I Get Started? Innovation Ecosystem

While a typical **"ecosystem"** is made up of organisms and their environment, an **"innovation ecosystem"** describes the various players, stakeholders, and community members who are critical for innovation. These players often include academic researchers, small businesses, the investor community, and commercial industry. Each of these plays a vital role in creating value in the ecosystem by transforming new ideas into reality through access, support, and financial investment.

Just as organisms support each other in a typical ecosystem so they can function together and survive, players in innovation ecosystems help each other, too. These collaborations occur in a variety of ways, including events, cross-promotion, and sharing resources. Working together in this capacity demonstrates the power of collaboration and creates a community that supports each other's goals, missions, visions, and values.

How does the innovation ecosystem help to promote a culture of innovation and entrepreneurship at Texas Tech?

The Innovation Hub at Research Park (Hub), Office of Research Commercialization (ORC), Small Business Development Center (SBDC), and the Office of Research Services (ORS) offer numerous programs and educational events throughout the year targeted toward the Texas Tech community and the broader West Texas region to help better establish Texas Tech as the go-to place for innovation. This is accomplished primarily in the following ways:

- Workshops, seminars, and speaker series hosted throughout the year on new venture creation, business planning, and patenting your technology.
- Early stage funding opportunities, such as the Texas Tech Research Park, Inc. Seraph Hub Fuel Fund.
- The TTU Accelerator, providing education, grant money, mentorship, and space to launch.
- The National Science Foundation Innovation Corps (NSF I-Corps[™]) program designed to facilitate commercialization of university research and inventions. Innovation Hub invites up to 50 teams per year to participate in the program.
- A state-of-the-art innovation hub, business incubator, and laboratory at the Research Park site that stimulates entrepreneurial activity and promotes the commercialization of research discoveries. Innovation Hub, ORC, and SBDC work closely together with centers, colleges, and community organizations to provide educational programs for members and the broader West Texas community.
- Assessing Texas Tech intellectual property and research discoveries, and marketing certain IP to facilitate industry relationships.

STEP 1: Engagement Portal ttuhub.incutrack.net/apply.cfm



STEP 3:

Identify initial destination/ introductions; engagement meetings

GAP PEPTIDES

"GAP Peptides' journey started in 2017 and many rollercoaster moments have marked our path. The support, the service, and the collaboration of the Team at the TTU Innovation Hub has been a constant that's helped make our progress sustainable!"



Cole Seifert, Founder & CSO

SUCCESS STORIES PCOS Diet pcos-diet.com

PCOS Team

Dr. Jennifer Phy, Associate Professor in the TTUHSC Department of Obstetrics and Gynecology

Dr. Jaou-Chen Huang, Professor in the TTUHSC Department of Obstetrics and Gynecology

Dr. Ali Chappell, who received her PhD from Texas Tech University in Nutritional Sciences



PCOS Diet Story by Kay Williams

The Texas Tech University Health Sciences Center is the birthplace of a dietary innovation for treating a common disorder linked to infertility in women. A startup headed by Dr. Jennifer Phy, D.O., a physician at the Center for Fertility and Reproductive Surgery and associate professor, is a recent recipient of a Presidents' Innovation Award. Her company, PCOS Diet, is based on an endocrinologybased research breakthrough to help restore and maintain the patients' hormonal and metabolic balance.

Dr. Phy says one out of ten women has polycystic ovary syndrome, commonly called PCOS. She describes it as causing some telltale symptoms that vary in severity among patients. They include irregular or prolonged menstrual periods, acne, and excess male hormone levels. She says ultrasounds provide images of another key factor for diagnosing the syndrome: follicles that look like a string of pearls within fertile ovaries that fail to regularly release eggs. In addition to often preventing women from becoming pregnant, PCOS can also keep them from being able to lose weight. Dr. Phy says, "Many patients I've seen who have this syndrome tell me they feel it's controlled their life and stolen their womanhood."

Dr. Phy says the PCOS Diet startup has been about a decade in the making. She was contacted in 2011 by registered dietitian and Texas Tech doctoral student Ali Pohlmeier Chappell, who was studying nutritional sciences with a focus on reproductive endocrinology. Chappell says she had struggled with infrequent periods and acne as a teenager until a doctor recommended she stop drinking milk to help clear her skin. She was surprised by how quickly that was effective. Later, she was diagnosed with PCOS by another doctor, who advised she would need to watch her weight but gave her no other information on the syndrome or how to manage it. Her goal in grad school was to understand more about PCOS and how certain foods, such as dairy and starch-based foods, might exacerbate the syndrome. After hearing about Dr. Phy's specialized PCOS training at the Mayo Clinic and TTUHSC, Chappell asked her if she was interested in doing further research into a possible dietary link.

Days after her initial meeting with Chappell, Dr. Phy saw a patient with PCOS who'd been through seven months of unsuccessful surgical and medication treatments for infertility. "Nothing else had worked," Dr. Phy says. "So I told her, 'I just spoke to a dietitian researching how certain foods like dairy and grains might not be so good for women with PCOS. Would you be willing to change your diet and see what happens?' She agreed, and I also gave her the same fertility pills that had done nothing for her for so long. The woman called back a month later and said she was pregnant with twins. I thought maybe that had been just a coincidence. But then I tried the diet for another patient who also got pregnant soon afterward, and then with three more patients—all successfully. And so I thought, 'Wow! I need to call Ali.'"

The pair received their first research grant in 2015 from the Laura W. Bush Institute for Women's Health within the Texas Tech University Health Sciences Center. Funding for further studies followed in 2017 with continued successful results for increasing both fertility and weight loss for most patients in the trials.

Dr. Phy and her team have been working with the Texas Tech Office of Research Commercialization since September 2019 and received a copyright. They are planning on applying for a patent when the web-based app is complete.

The website, pcos-diet.com, went live in January. The PCOS Diet received a \$10,000 Presidents' Innovation Award. The team has also received the TTU iLaunch Award, (\$10,000), was accepted into the TTU Innovation Hub Accelerator Program (\$25,000), and has contributed \$13,000 in personal investments. Dr. Phy says, "This funding will be a great help to us in moving forward. Making this information easily available and accessible to doctors and to patients with PCOS is a big part of my hustle, which is all about helping women who want to be mothers. My two children are the greatest joys in my life. I want others to have that kind of happiness in their lives, too." "The critical ingredient is getting off your butt and doing something. It's as simple as that. A lot of people have ideas, but there are few who decide to do something about them now. Not tomorrow. Not next week. But today. The true entrepreneur is a doer, not a dreamer."

- Nolan Bushnell

Ideation & Startup Creation

Do you have an idea, or do you want to be an entrepreneur? How do you find a team?

There's a lot to consider when becoming a founder of a new venture. The Innovation Hub (The Hub), Office of Research Commercialization (ORC), Small Business Development Center (SBDC), and the Office of Research Services (ORS) are resources for faculty, students, and entrepreneurs. The Innovation Hub team is dedicated to education for the development of your new venture and provides twelve programs at various points in the development process. The programs are divided into three areas: Ideation, Commercialization, and Acceleration. The programs, mentors, and the Hub staff provide guidance in the steps to founding a company.

Access and support of early stage ideas and creative and innovative research is accomplished in Ideation Programs. These programs focus on the "next steps" in development of taking an idea and making a real product. Introduction to presenting an idea, team formation, customer discovery and how to develop a value proposition are outcomes of the learning. The following ideation programs are free and open to all students, faculty, and community members. Stay updated on program application deadlines at <u>www.innovationhub.ttu.edu</u>.

Red Raider Idea Competition

Red Raider Idea Competition occurs annually in the fall. Applicants create a 60-second video and load it onto the Idea Competition website to be queued for a vote. Entrepreneurs will want all their friends to vote for their ideas to win a cash prize of \$2,000 for 1st place.

iLaunch Competition

iLaunch Competition is a competition for the next big idea with a \$10,000 1st prize. Applicants submit a 60-second video, executive summary, and a business model canvas pitch presentation. The iLaunch competition occurs annually in the spring.

Red Raider Startup

Red Raider Startup, an exciting threeday weekend program, is a great way for first-time entrepreneurs to get started. Over the course of the weekend, applicants form a team around an idea, validate the idea through customer discovery, create a pitch deck, and pitch to a panel of investors.

Faculty C-Startup program

Faculty C-Startup program is designed to support Texas Tech faculty interested in creating a culture of innovation and entrepreneurship. All applicants are evaluated by a committee of iTTU Mentors, Innovation Hub staff, and Texas Tech faculty. Faculty who are awarded the grants become "ambassadors" for innovation and entrepreneurship at Texas Tech for the academic year awarded. Applications open annually in the spring.



Hub Camp

Hub Camp is the next step once you have an idea and are ready to understand how to make money. A business plan is crucial for entrepreneurs to understand what is necessary to launch their startup. All participants are provided with a business plan template and access to the Innovation Hub expert mentors.

Discoveries to Impact (DTI)

Discoveries to Impact (DTI) is Texas Tech University's annual conference that brings participants together to showcase research, engagement, innovation, and business startups; compete for prize money for the best innovation and startup ideas; and hear from numerous thought leaders, intriguing panel discussions, and dynamic entrepreneurial speakers. To learn more about DTI visit <u>www.dti.ttu.edu</u>.

SUCCESS STORIES Envirostatus enviro-status.com

Envirostatus Team

Magdalena Rakowska, CEO, Civil, Environmental, and Construction Engineering Balaji Anandha Rao, COO TTU Department of Civil, Construction and Environmental Engineering Alex V Smith, CMO, TTU Dept. Civil, Construction and Environmental Engineering Danny D Reible, CTO, TTU Dept. Civil, Construction and Environmental Engineering



Envirostatus Story by Kay Williams

You could call it a labor of love. Texas Tech University researcher Magdalena Rakowska is passionate about environmental science and innovations that make it easy for everyone to understand the quality of their surroundings. That's the overarching mission of the startup she co-founded called Envirostatus, a technology company to reduce contaminants in water, sediments, and air. It's one of the companies in the 2019-2020 Texas Tech Accelerator program at the Innovation Hub.

Rakowska has a Ph.D. in environmental engineering. She met her husband, Balaji Rao, in 2014 while both were working as postdoctoral researchers with Danny Reible, Ph.D., who holds the Maddox Distinguished Engineering Chair in the Department of Civil, Environmental, and Construction Engineering. The trio still works on Texas Tech research projects. They are also co-founders of Envirostatus. The fourth member of the Envirostatus team is CMO Alex Smith, a graduate Ph.D. Research Assistant at the Department of Civil, Environmental, and Construction Engineering. Rakowska is the startup's CEO. She says, "Our company provides new technology in passive samplers that are designed for optimal performance, supporting deployments and retrievals, and streamlined data interpretation, providing convenient and cost-effective products for assessing contaminant bioavailability." She says the idea is to bring the science out of academia to the broader community. "It's so needed for other people to understand what we are doing, first of all, and how important it can be. Decisions are based on results. We have developed a method to make measurements understandable and more accessible. We want decision-makers to be able to use the data without hesitation and serve the purpose of their project." She adds, "In the future, the company may focus on personal devices that can measure an individual's exposure. I think through incremental steps, we can eventually go broader and change the mindset, be more protective of the environment, and accelerate more technologies that are environmentally friendly."

Rakowska's journey into the field of scientific research began in Poland. She credits her high school chemistry teacher as the first of many female role models that inspired her to pursue a career in STEM. She says, "I had women instructors even during my undergrad years that would talk about chemistry like it was some kind of wonderful magical art. They were very good at inspiring me. Once they had your interest, they would gradually dive into more detail. It was the feminine touch added to hard science that captured my imagination and encouraged me to explore it." Rakowska was recently featured in a local news story about women in the STEM field.

As for entrepreneurship and hustle, Rakowska says that inspiration began at home. "It is important to be raised in an environment where there's a lot of independence. That teaches you strength. My mom was a teacher, but then she went into an entrepreneurial business. Necessity is sometimes the mother of invention. My mom was amazing in teaching me that you can do it." Rakowska says her husband also provides inspiration. "He has been very supportive in research as well as in starting the company. He was the one who would say, 'Just start it up. Go for it.' He definitely gave me a thumbs-up to begin the process of applying for the TTU Accelerator program." She adds Dr. Reible and the team's mentors at the Innovation Hub are great encouragers. "Danny drives that hustle, especially for researchers, to explore the direction of commercial application. Our mentors help me get over the fear stage and gain confidence to go forward."

Envirostatus has worked with the Office of Research Commercialization to file a trademark and complete patent searches. The company has received \$78,000 in investments to date and is working on two SBIR grants to receive non-dilutive funding and hence become more attractive to Investors.

What is translating an idea for commercialization?

Commercialization is the process of introducing a new product or method to make it available to the market. The commercialization programs focus on nascent startups who have technologies and need to develop an alpha product with an intent for commercial use. An initial validation and assessment of product market fit is essential to prioritize market entry. The following commercialization programs are free and open to all students, faculty, and community members. Stay updated on program application deadlines at <u>www.innovationub.ttu.edu</u>.

Prototype Fund

Prototype Fund provides proof-of-concept grants for technology startups. The objective of the fund is to accelerate the development of a prototype for technology startups, assist TTU faculty, community, and students in furthering IP development as a result of the NSF I-Corps recommendations, and develop an MVP as a current or past participant in any Innovation Hub Program.

NSF I-Corps[™] VentureWell

The I-Corps[™] program was created by the NSF in 2011 to help move academic research it has funded to market. Through a dynamic collaboration with VentureWell, the NSF offers select participants from US academic laboratories the opportunity to participate in a special, accelerated version of Stanford University's Lean LaunchPad course. This revolutionary course engages participants in moving products out of the lab and into the market by talking to potential customers, partners, and competitors and encountering the challenges and uncertainty of creating successful innovations. Key videos: https://venturewell.org/i-corps/llpvideos/

TTU NSF I-Corps Site

TTU NSF I-Corps Site cultivates and supports startups by teaching program participants how to identify novel commercial applications for an idea or technology. Applicants interested in developing an idea, concept, or technology are encouraged to participate. The program identifies a customer segment for the technology and supports future funding opportunities. The program is hosted multiple times a year.

Steve Blank, founder of I-Corps methodology, video library

https://steveblank.com/category/lean-launchpad/

NSF I-Corps official webpage

https://www.nsf.gov/news/special_reports/i-corps/

How do I start a company?

The next step is the formation of a business entity. A business entity is an organization created by an individual or individuals to conduct business, engage in a trade, or partake in similar activities. Below is a checklist of activities for company formation. The list of tasks is covered in the annual TTU Accelerator program.

Create a company name
Check name availability and trademark availability
Buy domain name and find a website content management system
Register company with your state
Obtain an EIN
Open a business bank account
Execute an Operating Agreement
Execute a Management Agreement, LLC Agreement Amendment, and/or LLC Agreement Joinder

If your company is based on technology owned by Texas Tech University System:

Execute an Option Agreement

Execute a License Agreement

If applying for SBIR/STTR funding (see pages 49-53 for details):

Obtain a DUNS number*

Obtain a CAGE code

- Register company with eRA Commons
- Register principal investors with eRA Commons
- Register with grants.gov
- Authorize AOR
- Register company with sbir.gov

* The DUNS number is expected to be replaced by a Unique Entity Identifier (UEI) by April 2022. Entities with a DUNS number will automatically receive a UEI. Entities without a DUNS number will receive a UEI when registering in SAM.gov.

Resources to help start your company

Business plan template:

innovationhub.ttu.edu/ie/

Pitch deck template:

innovationhub.ttu.edu/ie/

Innovation Hub:

The Hub is a place to nurture the smart ideas of entrepreneurs to create a social or commercial value resulting in impact. The Hub assists in the formation of technology startup companies critically relevant to today's local and regional economy. Startups create >80% of new jobs, new industries, and new solutions.

Small Business Development Center (SBDC):

America's SBDC at Lubbock is hosted by Texas Tech University to provide no-cost business consulting and lowcost training to new and existing businesses. Small business owners and aspiring entrepreneurs can have face-to-face business consulting and at-cost training on a variety of topics.

Small Business Association (SBA) startup tools:

Plan your business : https://www.sba.gov/business-guide/plan-your-business

- Conduct market research
- Write business plan
- Calculate startup costs
- Fund business

Launch your business: https://www.sba.gov/business-guide/launch-your-business

- Choose business structure
- Choose a name
- Register business
- Federal tax ID
- Open business bank account
- Get business insurance

Manage your business: https://www.sba.gov/business-guide/manage-your-business

- Hire employees
- Pay taxes
- Marketing and sales
- Prepare for emergencies

Grow your business: https://www.sba.gov/business-guide/grow-your-business

- Get more funding
- Become a federal contractor
- Merge and acquire
- Prepare for emergencies

Business formation support and acceleration programs

Acceleration Programs

Acceleration programs move teams with a technology quickly through commercialization and support entrepreneurs through company formation, industry connections to the market, product testing, and initial customer revenue. Acceleration programs provide seed investment money, office space, subject matter expertise, and mentorship. All Acceleration programs are free and open to students, faculty, staff, and community members. Stay updated on program application deadlines at <u>innovationhub.ttu.edu/ie/</u>

Presidents' Innovation Awards

Presidents' Innovation Awards are grants from Texas Tech University and Texas Tech Health Sciences Center Presidents. The objectives of the grants are to: 1) provide programs for students and entrepreneurs; 2) offer seedstage funding for startups; and 3) provide seed grants to support equipment and rental expense at the Innovation Hub at Research Park (Hub). A committee of TTUS faculty, Hub staff, and TTUS facility staff determine the top applicant startups that exemplify innovation and commercialization. The committee reviews applicant budgets and offers recommendations that might or might not be reflective of the budget submitted in the application. Final decisions for awards are made by the TTU President and TTUHSC President. <u>innovationhub.ttu.edu/ie/</u>

Texas Tech Accelerator

Texas Tech Accelerator is designed to help faculty, students, and other entrepreneurs in the region launch startup companies or discover licensing opportunities based on inventions and university technology. Participating in the Texas Tech Accelerator is based on an application process that begins the previous spring. Participating companies have access to funding support, \$25,000 grants, co-working space, and mentors during the yearlong process. innovationhub.ttu.edu/ie/

Seraph Hub Fuel Fund

Seraph Hub Fuel Fund, a project of Texas Tech Research Park, Inc., invests in seed-stage companies in highopportunity technology markets—with a focus on agriculture—that can attract follow-on capital, create high growth companies primarily in West Texas, and generate strong financial returns. Hub Fuel Fund plans to invest in 25 to 35 Ag-Tech startups with investments ranging from \$100K to \$250K. The Hub Fuel Fund invests in startups offering a product that has a defined customer segment entry point with scalability and a proven business model strategy through sales traction. innovationhub.ttu.edu/ie/

How can I fund a startup?

When starting a company, generating funding to support the business is one of the most important tasks founders need to address. Before embarking on this task, it is necessary to determine how much funding your company needs and from where it will come. A typical startup goes through several rounds of funding, and at each round you want to take just enough money to reach the speed where you can shift into the next phase for the development of your startup.

Organic growth

Grow the business slowly based on sales without the need to raise external funds. Organic growth can be a reasonable strategy for certain new ventures. Typically, however, university innovations are at such an early stage of development that additional funds are necessary to move them from the lab to market.

Small Business Innovation Research grants (SBIR)

The US government provides innovation research grants to small companies, which can be great sources of initial capital. SBIR grants can only be provided to a company, not directly to an academic lab. More information can be found in the next section and in the Appendix.

Seed investment

Seed firms are like angels in that they invest relatively small amounts at early stages, but also like venture capitalists in that they are professional investment firms (often with investors of their own), rather than individuals making occasional investments on the side.

Venture capital funds

Venture capital firms are like seed firms in that they are professional investment firms, but they invest much larger amounts. They also typically invest in more established businesses. Venture capital investments involve millions of dollars, so they tend to come later in the life of a company, are harder to get, and come with tougher terms.

Angel investors

Individuals or groups that invest their own money in early-stage companies. Texas has several angel investor groups, including Lubbock Angel Network and Capital Factory. For a listing of angel groups in the region as well as other useful information, visit Innovation Hub staff to identify investors in the Pitchbook database.

What is SBIR/STTR?

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs

The SBIR/STTR program is a competitive funding mechanism available to US small businesses. The program is structured in three phases, only two of which are supported by the government through funding. Funding can come from either grants or contracts. Phase I awards are aimed at establishing the technical feasibility of a project and are usually six to 12 months in duration. Phase II awards are intended to continue the efforts of a Phase I award with specific emphasis on commercial development and the commercial potential of the project. These are two years in duration. The US Small Business Administration (SBA) serves as the coordinating agency for SBIR and STTR programs. Each agency administers its own individual program within guidelines established by Congress. These agencies designate R&D topics in their solicitations and accept proposals from small businesses. Awards are made on a competitive basis after proposal evaluation.

The focus of the SBIR program is to stimulate technology innovation by strengthening the role in federal research/ R&D. SBIR program goals are four-fold:

- Stimulate technological innovation.
- Use small businesses to meet federal R&D needs.
- Foster and encourage participation in innovation and entrepreneurship by socially and economically disadvantaged small businesses.
- Increase private-sector commercialization of innovations derived from federal R&D funding.



SBIR

The SBIR program was established to strengthen the role of innovative small business concerns (SBC) in federally funded research and development (R&D). To qualify for the program, the business must be:

- Organized for-profit, with a place of business located in the United States;
- At least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, OR
- At least 51% owned and controlled by another forprofit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and
- No more than 500 employees, including affiliates.

sbir.gov

SBIR The SBIR Program is structured in three phases:

Phase I

The objective of Phase I is to establish the technical merit, feasibility, and commercial potential of the proposed R/R&D efforts and to determine the quality of performance of the small business awardee organization prior to providing further federal support in Phase II. SBIR/STTR Phase I awards are generally \$50,000 to \$250,000 for six months (SBIR) or one year (STTR).

Phase II

The objective of Phase II is to continue the R/R&D efforts initiated in Phase I. Funding is based on the results achieved in Phase I and the scientific and technical merit and commercial potential of the proposed project. Typically, only Phase I awardees are eligible for a Phase II award. SBIR/STTR Phase II awards are generally \$750,000 for two years.

Phase III

The objective of Phase III, where appropriate, is for the small business to pursue commercialization objectives resulting from the Phase I/II R/R&D activities. The SBIR/STTR programs do not fund Phase III. At some federal agencies, Phase III might involve follow-on non-SBIR/STTR-funded R&D or production contracts for products, processes, or services intended for use by the US government.

Each year, federal agencies with extramural R&D budgets that exceed \$1 billion are required to reserve 0.3 percent of the extramural research budget for STTR awards to small businesses. Currently, five agencies participate in the STTR program:











Department of Defense

Department of Energy

Department of Health & Human Services

National Aeronautics & Space Administration

Department of Education

<u>sbir.gov</u>

Key differences between SBIR/STTR programs

STTR differs from SBIR in three important aspects:

The small business awardee and its partnering institution are required to establish an intellectual property agreement detailing the allocation of intellectual property rights and rights to carry out follow-on research, development, or commercialization activities.

STTR requires that the small business perform at least 40% of the R&D and a single partnering research institution perform at least 30% of the R&D.

STTR program allows the principal investigator to be primarily employed by the partnering research institution.

SBIR/STTR hint

1

Note that while the discussion here focuses on NIH, many other government agencies offer SBIR/STTR programs. Some, such as the DoD, have large budgets. Take your time in searching <u>sbir.gov</u> and <u>grants.gov</u> as well as the other agencies' sites for a grant opportunity that really fits what you are doing. Once you identify such an opportunity, we suggest you establish a connection with the program officer in charge and discuss your intended application months ahead of time. The program officer can be instrumental in suggesting an angle that is of interest to the agency and become your advocate in that agency.

SBIR/STTR contract

An SBIR/STTR funding agreement is a contract, grant, or cooperative agreement entered into between an SBIR/STTR participating federal agency and a small business for the performance of research or experimental or developmental work funded by the federal government.

sbir.gov

"It's not that we need new ideas, but we need to stop having old ideas."

- Edwin Land

Inventions, Intellectual Property, & Licensing

What is an invention?

An invention is generally something new that has been created outside of what currently exists or as an improvement to current solutions. The United States Patent and Trademark Office (USPTO) categorizes inventions as new processes, methods, compositions of matter, or articles of manufacture. Additionally, inventions can come in the form of original works of authorship (such as computer code, film, or literary works) or even new tradenames for a product, business, or service. If it is something you have created, chances are it qualifies as an invention.

What is an invention disclosure?

An invention disclosure is the formal disclosure of an invention or discovery to the ORC. The disclosure consists of a completed Invention Disclosure form and other relevant information that describes the invention or the research being conducted. This other information might include manuscripts, grant proposals, or even presentation slide decks.

Typically, university employees are required by policy to file an invention disclosure with the ORC in the event a research discovery has been made or an invention is created, and the university owns all intellectual property related to your employment. Undergraduate students and non-employees of the university are not obligated to file an invention disclosure with the ORC but can elect to do so as part of participation in a program at the Innovation Hub. The full Patent Policy is discussed later in this guidebook as well as in the TTUS Regents' Rules.

The Invention Disclosure form captures key points of interest such as funding sources, inventorship, how the invention might be used, and past public disclosures of the invention that have been made. ORC uses the completed form, along with other provided information, to evaluate the patentability and the commercial market potential of the invention, culminating in an Assessment Report, which is shared and discussed with the inventor. Inventor comments on the Assessment Report are highly encouraged and can be used to facilitate commercialization of the technology and filing of a patent application or copyright to protect the intellectual property. Additional details are available at https://www.depts.ttu.edu/research/commercialization/inventors/index.php.

How do I submit an invention disclosure?

An editable pdf of the Invention Disclosure form can be downloaded on the ORC website at: <u>https://www.depts.ttu.edu/research/commercialization/</u>inventors/downloads/TTUORCEditable-Invention-Disclosure-Form.pdf.

Please complete as much of the form as possible, then submit it, along with any accompanying information, to the ORC through the Invention Disclosure Portal or by email to patents@ttu.edu. You can also email it directly to any ORC Licensing Associate if you have already spoken to someone in the office about your discovery.

Additional information about the disclosure processes can be found on our website at: <u>https://www.depts.ttu.edu/</u> research/commercialization/inventors/submitdisclosure.php.

Reproductive Solutions

"Our startup journey is unique. We worked for 10 years to develop the technology we licensed from our alma mater. They were the best partner we could have envisioned. They stayed with us, encouraging us, supporting us, cheering us, being flexible with us...and now we are going global, partially, as a result of their patience and support."

- John Smothers, CEO

SUCCESS STORIES Moonlight Therapeutics moonlighttx.com

Moonlight Therapeutics Team

Dr. Harvinder Singh Gill, Co- Founder, Associate
Professor of Chemical Engineering TTU
Samirkumar Patel, CEO
Dr. Vladimir Zarnitsyn, CEO
Murali Anantharaman, MBA CFO



Moonlight Therapeutics Story by Abby Stone

"The idea was developed when Dr. Gill, who has expertise in microneedles, first pioneered their use for the treatment of respiratory seasonal allergies," Patel said. "In 2015, Dr. Gill received a \$1.8 million grant from the National Institutes of Health (NIH) to develop the microneedle technology for the treatment of seasonal allergies." As a unique extension, Gill proposed that, in addition to seasonal allergies, the same microneedle technology could also be used to treat peanut and other food allergies. Patel found out about this technology and became interested. Conversations ensued and the idea of commercializing the microneedle technology for the treatment of peanut and other food allergies was born.

The newly founded company sought assistance from the Office of Research Commercialization (ORC) in order to support the growth of Moonlight Therapeutics.

"The ORC recognized the unique challenges a life-sciences startup company must overcome," Patel said. "They were understanding of the challenges in developing this technology and worked with the team to file the IP and create flexible licensing terms that could benefit both the company and university. The ORC continues to support the healthy growth of the company."

Moonlight Therapeutics now has patent applications filed in the US and abroad. The company is actively working to expand its portfolio around the base IP it has licensed from Texas Tech. "The company was initially founded using personal investments by the founders," Patel said. "Our next major funding came from the NIH worth more than \$2.5 million. We applied for this money through the small business research program established by the NIH. We closed our first private round of funding in the spring of 2020 with a small group of individual investors and an angel network.

"Our immediate focus in the company is on completing the preclinical development for the treatment of peanut allergies. "This includes developing robust methods and data around the production of the patch containing our proprietary peanut allergen formulation, and the safety and tolerability of this patch." This data will allow us to discuss with the Food and Drug Administration the evaluation of our treatment in our first human clinical trial. The purpose of this trial will be to evaluate the safety and tolerability of our treatment in peanut-allergic children and adults. The data from this first human study will allow us to perform a Phase 2 clinical study to evaluate the efficacy of the treatment in allergic individuals."

Why submit an invention disclosure?

The ORC is responsible for filing patents to protect university-owned intellectual property. Patents and other forms of intellectual property improve the chances that a lab discovery will have a real-world impact. Consideration for patent protection begins with filing an invention disclosure, so this is an important first step in commercializing any invention. Few technologies that are unprotected by patents or copyrights are ever licensed and successfully commercialized.

Technologies that are licensed and brought to market generally create a stream of income through the payment of royalties to the university. The inventor(s) of the technology receive 40% of all net revenue generated through a license agreement, so there is a financial incentive for your efforts to disclose and protect your invention.

University employees are required by policy to disclose all inventions and discoveries to the ORC to determine if intellectual property protection is available and warranted.

When should I complete an invention disclosure?

Inform ORC of your invention and submit the Invention Disclosure form prior to any public disclosure, as required by the TTUS Patent Policy. It is never too early to talk with ORC. Inform ORC of your invention even if the research is in the concept stage, ORC can help develop the IP landscape to strengthen future proposals. Ideally, an invention disclosure is made prior to any public release—such as a poster presentation, conference, or publication—of the idea. Public disclosure of an invention in any form before filing a patent can restrict or eliminate the ability to obtain a patent. (Yes, this even applies to undergraduates in your lab presenting posters at research week.) Inform ORC of any imminent or prior public disclosures, such as a presentation, lecture, poster, abstract, research proposal, thesis, publication, or any other type of public presentation which includes the invention. If you are unsure or have any questions about making an invention disclosure or what constitutes a public disclosure, contact the ORC.

Engagement meetings

If you have a new invention disclosure, have questions about making a disclosure, or are exploring a new commercialization idea, a meeting should be scheduled with either ORC or the Innovation Hub to review the project and coordinate next steps. When appropriate, a representative from ORC or the Innovation Hub might reach out to researchers whose projects align with the generation of intellectual property or appear to have strong commercial potential.

- 1. Review the idea or research project to better understand its significance, applications, and commercial potential.
- 2. Determine potential intellectual property—such as patents, copyrights, trademarks, or trade secrets—within the project.
- 3. Discuss the appropriate path forward for the idea. Faculty and labs typically work with ORC to generate an invention disclosure while students, entrepreneurs, and community members typically work with the Innovation Hub via their commercialization programs to further validate an idea's potential. Faculty and lab researchers are also encouraged to participate in these programs.
- 4. Coordinate a timeline with ORC to balance an assessment and potential patent protection with your development path and plans to publish or present the technology at conferences.

Patents

What is a patent?

In the United States, the owner of an issued patent has the right to exclude others from making, using, selling, offering to sell, or importing the patented invention. This right is not automatic and may need to be actively enforced or defended by the patent owner. A patent does not provide the owner with any right to practice a technology that falls under a broader patent owned or controlled by others. The specific claims of an issued patent define the legal scope of the owner's protectable invention. <u>https://www.uspto.gov</u>

What type of subject matter can be patented?

Patentable subject matter includes processes, machines, compositions of matter, articles, some computer programs, and methods (including methods of making compositions, methods of using a process or material, and so on).

What is the United States Patent and Trademark Office (USPTO)?

The USPTO is the federal agency, organized under the Department of Commerce, that administers the patent system on behalf of the government of the United States. The USPTO employs patent examiners skilled in all technical fields to evaluate patent applications. The USPTO also issues federal trademark registrations.

What is the definition of an inventor on a patent, and who determines this?

Under US law, an inventor is a person who takes part in the conception of the invention(s) claimed in the patent application. Accordingly, inventorship can change as the patent claims are changed during prosecution of the application. A person who only furnishes the funds to build or practice an invention or who is directed by another to perform a specific task or series of tasks is generally not an inventor. Likewise, rarely are all authors on a paper or article inventors.

Who is responsible for patenting?

ORC contracts with external patent counsel for the protection of inventions owned by the university. This assures access to skilled patent specialists across a wide range of technology areas. Inventors typically work collaboratively with ORC and patent counsel in drafting the patent applications and formulating responses to patent office questions and feedback. ORC selects and oversees outside patent counsel.

What is the patenting process?

Patent applications are generally drafted by a patent attorney or a patent agent (a non-attorney with a science education licensed to practice by the USPTO). The ORC will typically ask you to review an application before it is filed and ask you questions about inventorship of the invention(s) claimed in the application. At the time an application is filed with the USPTO, the ORC will ask the inventor(s) to sign an Inventor's Declaration and an Assignment, which evidences the inventor's assignment to TTUS of the inventions claimed and any patent(s) that are issued. Patent applications can be filed in the United States and/ or in other countries, and the required paperwork might differ. ORC will typically seek inventor input and keep you informed regarding which jurisdictions patent applications are filed, especially on applications that are licensed.

Is there such a thing as a provisional patent?

No. However, there is a provisional patent application. Since a patent can only be issued to the first inventor to file an application, it is important to secure an early filing date prior to public disclosure. A provisional patent application is a type of patent application that secures a filing date for the application and reserves the applicant's right to file a later, more detailed nonprovisional application without negatively impacting the length of the patent term if a patent ultimately issues. A provisional application automatically expires after 12 months.

What is the difference between a provisional patent application and a regular (or "utility") patent application?

US provisional patent applications can provide a valuable tool for preserving patent rights while allowing for further development and refinement of the claimed invention. This useful feature of provisional patent applications occurs because the application preserves an inventor's priority filing date, but the provisional patent application is not examined during the year in which it is pending. A regular non-provisional application must be filed within one year of the provisional filing to receive benefit from its earlier filing date. However, an applicant only receives the benefit of the earlier filing date for material that is adequately described and enabled in the original provisional application proposal, thesis, publication, or any other type of public presentation which includes the invention. If you are unsure or have any questions about making an invention disclosure, contact the ORC.

What's different about foreign patent protection?

Foreign patent protection is subject to the laws of each country, although in a general sense the process works much the same as it does in the United States. In most foreign countries, however, an inventor loses any patent rights if the invention is publicly disclosed prior to filing the patent application. By contrast, the United States has a one-year grace period which may allow for some protection of patent rights for publicly disclosed inventions.

Is there such a thing as an international patent?

Although an international patent does not exist, an international agreement known as the Patent Cooperation Treaty (PCT) provides a streamlined filing procedure for most industrialized nations. A PCT application preserves the applicant's right to file in domestic and certain foreign jurisdictions. For US applicants, a PCT application is generally filed one year after the corresponding US application (either provisional or regular) has been submitted. Eighteen months after the PCT is filed (30 months after the provisional is filed), the application must be filed in the national patent office of any country in which the applicant wishes to seek patent protection.

The PCT provides two main advantages:

- It delays the need to file costly foreign applications until the 30-month date, generally providing the applicant with ample opportunity to further develop, evaluate, and market the invention for licensing.
- The international preliminary examination often allows an applicant to receive early feedback about patentability of the invention.

An important international treaty called the Paris Convention permits a patent or PCT application filed in a second country to claim the benefit of the filing date of an application filed in a first country. However, pursuant to this treaty, these so-called "convention applications" must be filed in foreign countries (or as a PCT) within one year of the first filing date of the US application.

What is the timeline of the patenting process and resulting protection?

Currently, the average utility patent application remains pending for about two years, although inventors in the biotech and computer fields should plan on a longer waiting period. If the utility application is filed in the US, depending on the type of technology, the patent attorney usually receives written notice from the USPTO in one to two years as to whether the application and its claims have been accepted as filed.

More often than not, the USPTO rejects the initial application because either certain formalities must be corrected or the claims are not patentable over the "prior art" (anything that scientists in the field have made or publicly disclosed in the past). The letter sent by the USPTO is referred to as an Office Action or Official Action. If the application is rejected, the patent attorney must file a written response, usually within three to six months. Generally, the attorney can amend the claims or explain why the USPTO's position is incorrect. This procedure is referred to as "patent prosecution." It can often take up to two USPTO Official Actions and two responses-and sometimes more-before the application is resolved. During this process, input from the inventor(s) is often needed to confirm the patent attorney's understanding of the technical aspects of the invention or the prior art cited against the application.

Patent applications are kept confidential for a period, but they are typically published 18 months after the first provisional patent is filed. After an application is published, the full application and information about prosecution can be found on the patent office website (<u>www.uspto.gov</u>).

Once a US patent is issued, it is usually enforceable in the United States for 20 years from the initial filing of the non-provisional application or PCT application, assuming that USPTO-mandated maintenance fees are paid during that 20-year period. There are some exceptions to this general statement, particularly involving inventions in the pharmaceutical fields. Contact ORC for more specific information about your invention or patent.

Can a provisional patent application, regular utility patent application, or PCT application be enforced or used to exclude others from practicing my invention?

No, patent applications cannot be enforced. Only a validly issued patent can be enforced or used to exclude others from practicing the claimed invention.

Why does ORC protect some intellectual property through patenting?

Patent protection is usually highly desirable for a potential commercialization partner (licensee) because it can protect the commercial partner's often sizable investment required to bring the technology to market. However, not all inventions are patentable or justify the significant expense and effort required to seek patent protection. ORC carefully reviews both the patentability and commercial potential of an invention before investing in the patent process.

Who decides what gets protected?

ORC and the inventor(s) usually jointly consider relevant factors necessary to make decisions relating to the potential filing of a patent application. If your invention was made using sponsored research funds, ORC might also consult with the funder(s). Ultimately, however, ORC makes the final decision as to whether to file a patent application, seek another form of legal protection, or decline to pursue through ORC.

What is the cost of obtaining a patent?

Filing and prosecuting a regular US patent application through to issuance can cost between \$15,000 and \$30,000, on average. Filing applications and obtaining issued patents in other countries may cost \$30,000 or more per country per application, on average. Once a patent is issued in the United States or in foreign countries, maintenance fees are also required to be paid every few years to keep the patent valid and enforceable.

What if I created the invention with someone from another institution or company?

If you created the invention under a sponsored research or consulting agreement with a company, the ORC licensing associate must review that contract to determine ownership and other rights associated with the contract and to determine the appropriate next steps. Should the technology be jointly owned with another academic institution, TTUS will usually enter into an interinstitutional agreement that designates one of the institutions to take the lead in protecting and licensing the invention and provides for sharing expenses associated with the patenting process and allocating licensing revenues.

If the technology is jointly owned with a company or foundation, or in some cases if a company or foundation funded the university research but did not participate in the research which led to the invention, the licensing associate will consult with the company or foundation to determine the appropriate patenting and licensing strategy.

Will the university initiate or continue patenting activity without an identified licensee?

Based on its evaluation, the university might elect to accept the risk of filing and protecting a patent application without an identified licensee. After university rights have been issued to a licensee, the licensee generally pays the patenting expenses that have been incurred up until the time of license (historical costs) and any patent expenses from the time of license forward (ongoing expenses).

The university sometimes decides to cease further patent prosecution and expense after a reasonable period of attempting to identify whether a license has transpired or if it is determined that it is not possible to obtain commercially valuable issued claims from the USPTO.

What terminology is used to describe the protection of intellectual property?

Tangible research materials

Tangible research property or materials describe unique materials that are owned by and typically created at TTUS. Most often, tangible research property or materials refers to biological materials such as specialized or unique reagents, cell lines, plasmids, or vectors, but it can also pertain to chemical compounds. Tangible research property might or might not be eligible to be protected by a patent. For more information, see the TTUS Regents' Rules.

Know-how

Know-how is distinct from patents, copyright, and trademarks because it generally refers to the technical knowledge and skill required to perform a task. It can also refer to nonpublished data, information, protocols, techniques, methods, processes, procedures, trade secrets, chemical structures, sequences, or other types of knowledge. Know-how often resides with certain faculty members or other individuals and thus can sometimes be difficult to transfer to third parties and even harder to protect. In some cases, the know-how can be identified or reduced to writing, such as when it refers to protocols or certain data.



What is a copyright and how is it useful?

A copyright is an intangible property right used for an original work of authorship that is fixed in a "tangible means of expression." Common forms of "tangible means of expression" include books or other written media and videos. Copyright protection attaches when the original work of authorship is fixed in a tangible means of expression, whether the work is published or unpublished. Copyright protects the way in which an idea is expressed but not the idea itself. Similarly, for a computer program, the copyright covers the source and object code but not the processes that the code causes a machine to perform.

Owning a copyright for an original work can be a valuable right because typically only the owner of a copyright or an individual with the owner's permission can make copies of the work and distribute the work publicly through print or electronic media. For performing arts and visual art, only the copyright owner or someone with permission can publicly display or publicly perform the work.

A US copyright lasts for a long time. For many works created in the US after January 1, 1978, the copyright is in effect for the author's life plus 70 years. *

TTUS recognizes faculty, staff, and students' freedom with respect to their copyrightable works, consistent with their obligations to TTUS **(Regents' Rules 10.03.3)**.

Who owns a copyrightable work created during employment or study at an institution of TTUS?

TTUS encourages the preparation and publication of copyrightable works that result from teaching, research, and scholarly and artistic endeavors by TTUS faculty, staff, and students. TTUS recognizes faculty, staff, and students' freedom with respect to their copyrightable works, consistent with their obligations to TTUS (Regents' Rules 10.03.3). Generally, TTUS owns works created as works for hire, works created under the scope of employment with TTUS, and works created with use of TTUS resources and encourages faculty publication and ownership of such works. Major exceptions to this include pedagogical, scholarly, or artistic works, regardless of their form of expression. For software and computer code, options include publication, allowing academic use, making them available as open source or in the public domain, or commercialization through ORC.

What is a derivative work as it relates to copyrights?

In most circumstances, a copyright owner is also the only person who can prepare or give permission for the creation of a "derivative work." A "derivative work" is an original work of authorship based on the material protected by the original copyright which expands, abridges, or makes other copyrightable modifications to the original work. Some common examples of a derivative work include a French translation of an English novel or poem, a movie screenplay based upon the original mystery novel, or the rewriting of computer code in a different computer language. If the copyright owner grants permission to prepare a "derivative work," only the new original material can be the subject of a new copyright and the original owner retains the copyright in the existing work. *

How do I represent a proper copyright notice?

Legally, works that are eligible for copyright are protected as soon as they are fixed in a tangible medium (for example, written on paper or saved as a computer file). Thus, whether a formal copyright application is filed or a copyright notice is included, copyright protection often exists automatically. Nonetheless, ORC recommends that authors include a copyright notice with the original work. Depending on how the original work is presented, the notice can be 1) written on the publication; 2) included on the website; 3) added as a text graphic on a video; 4) added as a statement on an audio file; or 5) included in the program for a performance of the work. *

If the copyright is owned by TTUS, the following notice should be used:

© [insert current year] Texas Tech University System. All rights reserved.

A similar notice can be used for an individually owned copyrights, substituting the author's name for Texas Tech University System. It is advisable to include the author's contact information with the copyright notice to make it easier for individuals who want to use the copyrighted materials to request permission.

A copyright can also be registered with the US Copyright Office at any time during the life of the copyright. However, registration is not required and is important primarily if a copyright owner wants to enforce copyright against someone allegedly infringing their copyright.

TM Trademark

What is trademark registration?

In the United States, a trademark can be registered at the state or federal level after the claimed owner files an application. At the federal level, trademark registration is a procedure in which the United States Patent and Trademark Office (USPTO) examines the filed application and determines whether the applicant has a right to use a trademark and to exclude others from using the same or a confusingly similar mark for the same or similar goods or services.

Trademarks generally become protectable once they are adopted and used in commerce to identify specific goods or services and begin to build goodwill, all of which can occur before one files an application or receives an issued trademark registration. With a federal trademark registration, the registrant is presumed to be entitled to use the trademark throughout the United States for the goods or services for which the trademark is registered. However, it is not necessary to register a trademark or service mark to build rights in a trademark or to prevent others from infringing upon the trademark. Like patents and copyrights, trademark rights typically must be enforced through litigation. Once you adopt a name, logo, or symbol as a trademark and use it in commerce to identify goods or services, you may place the "TM" symbol after the trademark. However, it is a federal crime to use the TM symbol unless and until you receive an issued federal trademark registration. *



The Office of Research Commercialization (ORC) team is committed to having every invention and discovery from our researchers reach its full potential. Our mission is to maximize the impact of TTUS research, innovations, and inventions on society. We also pride ourselves on being business-friendly when it comes to licensing TTUS intellectual property and transferring it to industry.

ORC works to effectively commercialize technologies and innovations by licensing TTUS technologies to established companies or startups and by helping researchers to attract and build industry partners. Turning intellectual property into a licensable asset is the key to facilitating commercialization at a research university.

What is a faculty member's role during commercialization?

The role of a faculty member can vary depending on need, interest, and involvement; the interests of the licensee in using faculty services for various assignments; and any contractual obligations related to the license or development agreements. Examples of continuing faculty involvement include sponsored research or joint development collaboration activities with licensees, scientific advisory, or consulting relationships, or joint venture formation activities.

ORC and the inventor will determine the best commercialization strategy, which might include licensing to industry, starting a company through resources at the Innovation Hub, or pursing a corporate partnership, often with the involvement of the Office of Sponsored Projects and Office of Research Services.

Marketing

Once patents have been filed and the technology has been protected, the ORC Licensing Associate assigned to your technology begins to market your technology to potential business partners. ORC completes a technology assessment for each invention disclosure we receive to evaluate patentability and identify potential business partners and licensees. These companies are our first contacts for potential interest and feedback. Your active involvement can dramatically enhance this process. Faculty publications and industry presentations are excellent marketing tools, and we send those to potential partners to help promote our technologies.

Industry outreach

ORC creates a nonconfidential technology summary and posts the technology on Flintbox, a worldwide subscriptionbased technology scouting platform that can be reviewed by potential licensees looking for technology solutions. You can view your posted technologies at <u>technologies</u>. <u>texastech.edu</u>. ORC might also market your technology through partnering programs and industry showcase events that highlight your technology to targeted businesses, often with inventor attendance and presentation.

The ORC uses many complementary resources and strategies to identify potential licensees and to market inventions. Often inventor relationships with industry can help to identify potential licensees. Texas Tech alumni, the staff at the Innovation Hub, and other Texas Tech researchers also help to identify potential licensees.

ORC also participates in numerous industry conferences and events each year to meet with potential licensees and to obtain valuable feedback about our technologies.

Inventor involvement

In all cases, the ORC will market both the technology and our researcher. It is difficult to license a technology without the input and support of the inventor, and the ORC relies on your publications and participation in telephone conferences to explain how the technology works and its benefits to help market the technology to potential licensees.

In many cases, a company's first contact with TTUS is a phone call or email to the researcher based on a publication that has been read or presentation that was attended. In fact, studies have shown that the best licensing leads often come from the inventors. Whenever that happens, ORC encourages our inventor to engage our office early in the process to make sure that confidential information is protected and to gauge their interest in an opportunity to license the technology.

Licensing

A license agreement is a contract between ORC and a third party in which TTUS rights to a technology are transferred to the licensee company, without relinquishing ownership, for financial and other benefits. The ORC has two main goals in any license agreement:

- 1. To ensure that the technology is developed by the licensee for public benefit, complying with federal, state, and TTUS policies.
- 2. If successful, to provide a reasonable financial return to both TTUS and the inventors.

License agreements are used with both startup businesses and established companies.

For industry

As a first step in the process of licensing a technology, a nonconfidential summary is sent to companies that are likely to be interested in it based on other patents they hold or customer markets they serve. If a company expresses interest, they will be asked to sign a confidentiality agreement to protect our patent rights prior to receiving confidential information and moving on to receiving detailed discussions about the technology and copies of the filed patent applications.

If the company continues to be interested, a telephone call with the researcher soon follows and financial terms for an option or license agreement for the patent rights with the company are negotiated by ORC. An option agreement is sometimes used to enable a third party to evaluate the technology and its market potential for a limited time before licensing. An option agreement provides companies with a noncommercial, internal-use license for a fee. Standard features of a license typically include negotiated financial terms such as annual fees, milestone fees, royalties on product sales, and reimbursement of patent costs. The financial terms for industry license agreements are established based on the cost to develop the technology, its stage of development, projected incremental income that will be generated for the company, and market comps for similar industry technologies based on public databases and proprietary information.

For startups

Startups are newly created spin-out companies based around technology developed and licensed from TTUS. If creation of a startup is chosen as the optimal commercialization path, ORC works to assist the founders in negotiating flexible license terms to accommodate the unique needs of a new company.

Negotiating license terms with a startup company often requires substantially more care, and ORC strives to ensure the new company understands the obligations and responsibilities contained within the license agreement and to negotiate flexible financial terms that are fair and understanding of the limited financial resources most startup companies face. For example, equity might be accepted in the place of a license documentation fee at the discretion of the company and some payments to reimburse past patent expenses might be deferred over a longer timeframe.

For more information about startups, see "Ideation & Startup Creation" on p. 12. *

*Content provided by Penn Center for Innovation.



FAQs for licensing technology

What revenues are generated for the university through commercialization?

Most licenses have initial or intermediate licensing fees that are relatively modest until a product is ready for sale on the open market, especially for relatively cashstrapped startups. However, on rare occasions, these fees can reach hundreds of thousands of dollars immediately. Royalties on the eventual sales of the licensed products can generate significant recurring revenues, although it usually takes many years to occur. Equity, if included in a license, can also yield long-term returns, but only if a successful equity liquidation event occurs.

What happens to an invention if the licensee is unsuccessful in commercializing the technology?

Licenses, particularly exclusive ones, typically include performance milestones that, if unmet, can result in the termination of the license and return of the technology to TTUS. This termination sometimes allows for subsequent licensing to another business. Licensees can also choose to sublicense all or a portion of their rights to another company to aid in commercialization and development of the technology that goes beyond the original licensee's capabilities and interests.

How long does it take to find a potential licensee?

For some technologies, potential licensees are immediately evident and interested, but for others, it can take months and sometimes years to find a licensee. When locating a potential licensee, important factors to be considered include the novelty and impact of the invention, its stage of development, competing technologies, and the size of the market. Most university inventions tend to be at an early stage of development and thus require substantial development and commercialization investments, which can make it challenging to attract and secure an immediate licensee.

What activities occur after a technology is licensed?

Most licensees continue to develop an invention to enhance the technology, reduce risk, demonstrate reliability, and satisfy the market requirements for adoption by customers. This process can involve additional testing such as prototyping, clinical trials, and further refinement to improve performance. Documentation for training, installation, and marketing is often created during this phase along with benchmarking efforts to demonstrate the product/service advantages and to position the product in the market.

Can there be more than one licensee?

Yes. An invention can be licensed to multiple licensees, either non-exclusively to several companies or exclusively to several companies, each for a unique field-of-use by application or by limiting the geographical place where the product or service can be provided.



Rights to intellectual property must be legally secured for any outside entity practicing or pursuing the technology. The most common way of securing TTUS-owned intellectual property is by securing a license to practice the technology. ORC and the outside entity typically engage in the following steps to license the technology.



- Execute Option Agreement if company (or team) is still in validation stage of technology.
- Exchange and negotiate Term Sheet based on company intent and business plan.
- Agree to terms and draft full exclusive or non-exclusive License Agreement.
- Execute License Agreement to company.

Non-Disclosure Agreement (NDA) or Confidentiality Agreement (CDA)

What is an NDA (non-disclosure agreement)?

An NDA (sometimes also called a CDA) is a binding legal agreement between two or more parties. This might be TTUS and a third party or you individually and a third party. The agreement defines confidential information, allows the parties to exchange confidential information, defines what each party can or cannot do with the other party's confidential information (for example, not share it with others that are not already bound to the same terms of confidentiality), and defines the purpose of the proposed sharing of information between the parties. In general, the purpose of a CDA is to protect discussions prior to a planned follow-on action by the parties, such as a research collaboration or license. Importantly, CDAs can protect the patentability of any proprietary information, patent, patent application, data, or know-how that has not yet been published. Without this type of protection, valuable intellectual property rights might be irretrievably lost.

When would I need an NDA?

Any time that you know or suspect that you will be discussing unpublished data, information, or know-how with a third party for any reason, an NDA is advisable. When first discussing a relationship with a third party, a non-confidential discussion is strongly suggested to allow the parties to have a better understanding of the proposed transaction and to ascertain whether there is sincere interest in conducting a more in-depth discussion. Two examples of appropriate times to enact an NDA are:

- When you want to receive or share a nonpublic research protocol before deciding whether to serve as a site in a clinical trial.
- When you want to share unpublished research with a potential sponsored research funder so the potential funder can learn more about your current research interests.

Options, term sheets, & MOUs/letters of intent

What is an MOU/letter of intent?

A memorandum of understanding (MOU), sometimes referred to as a letter of intent, is an initial agreement setting forth the basic terms and conditions under which TTUS can establish more formal contractual relationships with outside parties. An MOU typically defines how intellectual property will be shared and the relative roles and responsibilities of the involved parties. MOUs are often favored over term sheets when the business arrangement is a less structured collaboration rather than a straightforward license agreement. *

What is an option?

Option agreements, or option clauses within research agreements, describe the conditions under which the university grants a right for a limited period for the option holder to negotiate a license for TTUS-owned intellectual property. Option clauses are often provided in sponsored research agreements to corporate research sponsors so that the corporate sponsor obtains an exclusive, contractual, first right to negotiate a license to any intellectual property that is discovered in the course of funded, sponsored research. Option agreements are also enacted with third parties who wish to evaluate a technology prior to finalizing a full license agreement while also preserving their opportunity to negotiate an exclusive or nonexclusive license from ORC during the period of the option. An option agreement does not generally allow a company to use the technology in any commercial manner.

What is a term sheet?

A term sheet is a written understanding between the ORC and a potential licensee, setting forth the basic financial terms and conditions under which a TTUS technology could be licensed to an outside party. A term sheet often serves as the initial offer upon which a more detailed legal document, such as a patent license agreement, will be drafted with the help of the legal team. A term sheet helps to facilitate agreement between the parties on major agreement terms helping to avoid misunderstandings in subsequent negotiations. *

*Content provided by Penn Center for Innovation.

Licenses

What can I expect to gain if an invention I made is licensed?

Most inventors enjoy the satisfaction of knowing their inventions are being developed for the benefit of the public. New and enhanced relationships with businesses are another outcome that can augment one's teaching, research, and consulting activities. In some cases, additional sponsored research funding and support can result. Additionally, as required by the Bayh-Dole Act and per system policy, a significant portion of any net income from a patent license is shared with the inventor(s).

What kinds of things can be licensed?

Generally, licenses include a grant of rights to a form of intellectual property such as an issued patent or pending patent application, a copyright, software, a device prototype, a tangible research material or reagent, a defined data set, and so on. *

Can know-how be licensed?

Because know-how often exists in the individual's mind and skillset, TTUS generally tries to avoid licensing know-how. If licensed, know-how is typically licensed solely on a non-exclusive basis and only where it can be reduced to a tangible form. *

License agreements

License agreements describe the rights and responsibilities related to the use and exploitation of intellectual property developed at TTUS by the party obtaining the license. University license agreements usually stipulate that the licensee should diligently seek to put the intellectual property to commercial use for the public good and provide a reasonable return to TTUS. License agreements can be exclusive—meaning that only that licensee has rights to exploit a particular technology in the licensed field—or non-exclusive, meaning that more than one licensee can obtain a license to the same intellectual property in the same field of use.

The distribution of net revenue is:



For additional information on how licensing income is distributed, please see the TTUS Regents' Rules, Section 10.12.

What is the relationship between an inventor and a licensee, and how much of my time will it require?

Many licensees request, and sometimes require, the active assistance of the inventor to facilitate their commercialization efforts, at least in the early stages of development. This assistance can range from infrequent, informal interactions to a more formal collaboration. Working with a new business startup in contrast to working with an established company can, and often does, require substantially more time, depending on your role in or with the company and your continuing role within the university. Under all circumstances, your participation with a startup or well-established company is governed by university policies.

Participation might require further inquiry to develop an appropriate management plan for mitigating conflicts and determining best measures to support your innovation and realize commercialization activities.

How is a company chosen to be a licensee?

A licensee is chosen by ORC in consultation with the inventors, based on its ability to commercialize the technology for the benefit of the public. Sometimes an established company with experience in similar technologies and markets is the best choice. In other cases, the focus and intensity of a startup company is a better option.

Texas Tech University System patent policy

TTUS' patent policy is governed by Chapter 10 of the TTUS Regents' Rules which can be found at <u>http://www.</u> <u>texastech.edu/board-of-regents/regents-rules/chapter-10-intellectual-property-rights.pdf</u>. This summary is intended to provide a more accessible and user-friendly guide to how TTUS treats inventions created by faculty, staff, students, and other researchers in the course of their employment or research at any of the TTUS institutions. This summary and guide are presented for informational purposes only. The terms of the Regents' Rules are subject to change. In the event of a conflict between a statement in this summary and guide and the language in the Regents' Rules, the language in the Regents' Rules governs.

1. (Regents' Rules 10.05)

Researchers are required to disclose intellectual property with ORC.

2. (Regents' Rules 10.02.08)

ORC is responsible for administration and implementation of the TTUS intellectual property program; assisting and advising TTUS faculty, staff, and students regarding matters covered by this policy; and providing leadership and support through public and private sector engagement.

3. (Regents' Rules 10.01.05)

ORC is charged with system-wide responsibility of TTUS intellectual property.

4. (Regents' Rules 10.08)

ORC is required to assess the potential value of intellectual property to TTUS; the rights and equities of the creator, TTUS, and any third parties; and the required actions to maximize the benefits of any intellectual property to the public, TTUS, and the creator.

5. (Regents' Rules 10.04.1)

ORC is required to report federal funding.

MISSION (Regent Rule 10.01.4)

"...intellectual property owned by TTUS which has commercial value should be appropriately exploited to further the mission of TTUS."

What is the TTUS policy on inventions and patents?

Inventions and the related intellectual property created by faculty, students, TTUS employees, and visitors (such as visiting scientists or trainees) that are created 1) in the course of employment at a TTUS institution; 2) resulting from work related to professional responsibilities at a TTUS institution; 3) from work done on university time; or 4) with substantial use of TTUS resources from grants or otherwise are the property of Texas Tech University System, not the individual inventor. TTUS has the right to be made aware of, own, and manage any inventions and associated intellectual property created under one of the four categories listed above or otherwise set forth in the Patent Policy. Timely disclosure of inventions to the ORC is required.

What about student inventions?

Inventions made by students 1) in the course of employment at a TTUS institution; 2) resulting directly from work related to employment at a TTUS institution; 3) resulting from work under a grant or sponsorship requiring assignment to TTUS; or 4) where the invention is cocreated with another inventor who has a duty to assign the invention to TTUS, will be considered the property of the TTUS. Conversely, student inventions not falling under one of the categories above will remain the property of the student. All inventions resulting from research done in TTUS laboratories or facilities as part of a graduate or postdoctoral degree or non-degree program are the property of TTUS. Student inventors of inventions that are owned by TTUS are considered "creators" under the patent policy for purposes of sharing in distribution of revenues resulting from commercialization of inventions.

What about student or external inventions participating in Innovation Hub programs?

Inventions that are not owned by TTUS but are participating in commercialization programs at the Innovation Hub may still consult with the ORC and the ORC may provide initial technology assessment guidance to the team. Inventions owned by TTUS and participating in programs at the Innovation Hub are required to go through the assessment and protection process with the ORC, consistent with TTUS Patent Policy.

What happens to a technology when TTUS determines not to pursue or continue intellectual property protection?

Under certain circumstances, TTUS might decide that it either does not want to pursue a patent application, wants to abandon a previously filed and pending patent application, or does not wish to continue to own and maintain an issued patent. ORC will meet with and notify the inventor(s) to solicit feedback before making any final decision.

After consultation with the inventor(s), if TTUS still elects to abandon or not pursue the IP, the patent policy permits the possibility of inventor(s) to request that TTUS return ownership of the invention to them. The procedure for returning an invention and intellectual property to the inventor is outlined in TTUS Regents' Rules 10.08.1 and generally addresses TTUS retained rights, TTUS share of revenue, and reimbursement of TTUS investment in the IP up until release.

The possibility of release is often strongly influenced by whether there was federal or other outside sponsorship of the work leading to the invention. If there is no federal or other outside sponsorship, ORC might decide to return the right to the invention or patent, subject to the terms and conditions in the patent policy. If there was federal or outside sponsorship of the work leading to the invention, ORC might need to comply with certain requirements of the sponsor or funding agency, such as obtaining the consent of the funding agency before transferring its rights to the inventor. In addition, any return would remain subject to any of the rights that are retained by the federal government or outside sponsor of the invention.

Protecting Academic Freedom

Will I be able to publish the results of my research and still protect the commercial value of my intellectual property?

TTUS and ORC are strongly dedicated to protecting academic freedom and ensuring that faculty and researchers can freely publish and disseminate the fruits of their scholarship and research activities. However, since valuable patent rights might be affected or even destroyed by any public disclosure activities, it is best to submit an invention disclosure well in advance of communicating or disclosing your invention to people outside the TTUS community. In addition, there are significant differences between the United States and other countries as to how early publication affects a potential patent and how damaging a public disclosure can be to invention patentability. Once publicly disclosed (published or presented in some form), an invention might have no or minimal potential for patent protection outside of the United States. Within the United States,

prior disclosure within one year of patent filing does not necessarily eliminate patentability, but the ultimate value of a patent could be severely damaged, even within the United States, if it is not filed prior to any public disclosure. Be sure to inform the ORC licensing associate assigned to you of any imminent or prior presentation, lecture, poster, abstract, website description, research proposal submission, dissertation/thesis, publication, or other public presentation including the invention, and they can help to ensure that it is protected in a timely manner that does not restrict your ability to publish or discuss your invention publicly in any way. ORC can also help you verify whether any pre-publication review is required due to your sponsored research agreement and comply with any such requirement.*

*Content provided by Penn Center for Innovation.

May I use tangible research materials created by others?

Yes, if the other party is willing to share materials and any terms-of-use conditions the provider imposes are acceptable to you and TTUS. It is important to carefully document from whom and under what conditions you obtained materials so that we can help determine whether your use could impact the ownership rights of a subsequent invention or technology. In most cases, TTUS requires the use of an incoming material transfer agreement (MTA) for research materials being transferred into TTUS. MTAs are managed by the Office of Research Services (ORS) and information on submitting requests for materials can be found at <u>http://www.depts.ttu.edu/research/ors</u>.

What rights of us does a research sponsor have to any discoveries associated with my research?

A sponsored research agreement should specify the intellectual property rights of the sponsor. TTUS generally retains ownership of the patent rights and other intellectual property resulting from sponsored research. However, the sponsor might have a specified option to negotiate to obtain a license to the defined and expected outcomes of the research. Sponsored research contracts often allow the sponsor a limited time to negotiate for a license for any patent or intellectual property rights that result from the research. Sponsors generally do not have contractual rights to discoveries that are clearly outside of the scope of the research. Therefore, it is important to carefully define the scope of work within a research agreement. Sponsored research projects funded by non-commercial sponsors, such as the federal government or not-for-profit foundations, are handled by ORS. ORS project representatives work closely with ORC on intellectual property issues that arise from any sponsored research agreements that they manage.*

What about publication of results created under sponsored research agreements?

The ability to freely publish research results is fundamental to TTUS' mission as an academic research institution and is zealously guarded by the negotiators at ORC and ORS. In a sponsored research or clinical trial agreement, the corporate sponsor might be afforded a short period of time to review a pending publication or disclosure to protect their own confidential information or to allow the protection of certain rights to intellectual property, but sponsors are never provided with rights to unduly delay or prevent publication.

What about retained rights?

Pursuant to the Bayh-Dole Act, TTUS is required to retain certain research rights to continue to use licensed intellectual property where federal funding has been used in the development of such intellectual property, and to reserve rights—also known as march-in rights for the federal government to exploit the intellectual property under certain circumstances. In addition, it is TTUS policy to retain certain research rights in all of its licensed intellectual property to enable further research and clinical care, even if no federal funding was used in the creation of the licensed intellectual property.*

What if my research is federally funded?

Under the Bayh-Dole Act, TTUS maintains ownership of intellectual property even if it is the result of federally funded research. However, ORC and the inventor are required to report to the federal funding agency regarding the status of the patent or intellectual property, and the federal government does retain certain march-in rights, though they are rarely exercised.

*Content provided by Penn Center for Innovation.



Conflicts of Interest

When do research-related conflicts of interest occur?

It is state policy that state officers and employees cannot have direct or indirect interests, including financial and other interests, engage in business transactions or professional activities, or incur any obligation of any nature that is in substantial conflict with the proper discharge of the officers' or employees' duties in the public interest. TTUS has a centrally published policy governing research-related to Financial Conflicts of Interest (FCOIs) in Chapter 3 of the Regents' Rules at http://www.texastech.edu/board-of-regents/, regents-rules/chapter-03-personnel.pdf and specifically for TTU at https://www.depts.ttu. edu/opmanual/OP74.17.php. This policy is designed to identify and manage or eliminate financial conflicts related to specific research projects. Individual schools within TTUS might have additional policies regarding research-related conflicts of interest.

What are the investigator disclosure requirements?

Depending on your school affiliation, TTUS might have specialized electronic disclosure sites where you must provide information about your significant financial interests so a determination can be made on whether there is a financial conflict of interest and whether it can be managed. You must disclose significant business or financial interests (and those of your spouse or dependent children) that reasonably appear to be related to your field, discipline, or professional expertise. Specifics on the disclosure process at TTU are available at https://www.depts.ttu.edu/research/financial-disclosure/index.php.

What is a conflict of commitment?

A conflict of commitment refers to a situation where a TTUS employee engages in external activities, including service on an outside entity's board, either compensated or uncompensated, that interfere with the employee's obligation and responsibilities to TTUS. Employees shall evaluate and arrange their external interests and activities to avoid conflicts of commitment that would compromise their ability to carry out their obligations to TTUS. For more information, see TTUS Regents' Rules, Section 03.01.5.

To learn about the procedure for documenting other employment, see <u>https://www.depts.ttu.edu/opmanual/OP32.07A.pdf.</u>

Consulting

Certain institutional policies within TTUS allow for consulting with outside entities.

How is intellectual property handled when consulting?

TTUS encourages external faculty consulting as an effective mechanism for professional development or establishing good relationships with the public and private sector, including industry. However, a consulting agreement between a creator and a potential user, assignee, or licensee of intellectual property developed by the creator creates an inherent conflict of interest. Any creator who is a party to such a consulting agreement must fully disclose the existence and terms of such agreement to the creator's immediate supervisor and, with respect to intellectual property disclosed to the ORC, such disclosure to the ORC must include full disclosure of such conflict. Before entering into a consulting agreement, the TTUS employee must ensure that rights to intellectual property owned by TTUS are not compromised or lost because of the consulting activities. Further, consulting activities must not violate TTUS rules, regulations, or policies or federal or state law. (Regents' Rules, Section 10.03.2). The procedure for documenting other employment can be found at https://www.depts.ttu.edu/opmanual/op32.07a.pdf



Licensing Revenues

How are revenues from intellectual property agreements distributed?

Revenues from intellectual property agreements are distributed according to Section 10.12 of the TTUS Regents' Rules listed below. Exceptions are further discussed in the Regents' Rules, but generally include joint inventorship, external inventorship, or commercialization of copyrightable works. "Innovation is the process of turning ideas into manufacturable and marketable form."

- Watts Humphrey

Sponsored Research Activities

What are SRAs?

Sponsored Research Agreements (SRAs) are contracts that establish the terms and conditions under which the university accepts funding to support the conduct of defined research projects. SRAs governing research projects between the university and a corporate, for-profit sponsor are administered by the Office of Research Services (ORS) or Office of Sponsored Programs within TTUS institutions.

Who manages SRAs?

SRAs governing research projects between the university and non-profit organizations such as the government, National Institutes of Health (NIH), and foundations are administered by the Office of Research Services (http://www.depts.ttu.edu/research/ors/) and the Office of Sponsored Programs (https://www. ttuhsc.edu/research/divisions/sponsored-programs/ default.aspx). In addition, any language addressing intellectual property in SRAs is managed by the ORC.

How do I work with industry for sponsored research?

Texas Tech University System institutions provide administrative and management support for externally funded research proposals or sponsored projects. Sponsored projects include grants, contracts, and cooperative agreements from both the public and private sectors which support research and instructional and service projects.

- Texas Tech University: Office of Research Services (ORS)
- Texas Tech University Health Sciences Center: Office of Sponsored Programs
- Texas Tech University Health Sciences Center-El Paso: Office of Sponsored Programs
- Angelo State University: Office of Sponsored Projects

Whether working with federal, state, or private sponsors, the sponsored project life cycle begins with identifying funding and developing a scope of work and budget. When a sponsor decides to fund a project, an agreement is negotiated through the appropriate sponsored projects office.

When working with industry partners, an SRA is developed to establish the terms and conditions under which the university accepts funding to support the research projects. SRAs governing research projects between the university and a corporatate, industry, or for-profit sponsor are negotiated by the appropriate System Sponsored Projects Office. These offices work in collaboration with the Office of Research Commercialization to address any intellectual property language or considerations.



SUCCESS STORIES VXNed www.vxmedc.com

VxMed Team

Anthony Betteridge, CEO, TTUHSC medical student Nathan Lloyd, Chief Science Officer (CSO), TTUHSC medical student Jordan Ketring, CTO, TTU Computer Science masters program



VxMed Story by Kay Williams

Currently, textbooks and video lectures are the predominant modalities employed in medical education. Being forced to rely on these outdated learning methods to absorb mountains of information leaves many medical students feeling overwhelmed and burnt-out. VxMED is translating textbook and lecture medical knowledge into an interactive and enjoyable virtual learning experience.

Utilizing the latest VR technology, VxMED creates interactive clinical patient encounters, each of which features a unique 3D patient exhibiting the life-like symptoms of important diseases for medical students to master. As students interact with each virtual patient—identifying symptoms, ordering tests, suggesting treatment, and so on—their medical knowledge expands and their ability to care for patients improves.

The inspiration to advance medical education through a "learn by doing" virtual reality experience was born as co-founders Anthony and Nathan studied together for their medical licensing exams.

VxMED Software is available online. Access to in-game content is subject to a subscription, which can be purchased on our website, <u>http://www.vxmedc.com</u>.

Special thanks to the Texas Tech Innovation Hub for launching us on this grand adventure of transforming medical education. "Formal education will make you a living; self-education will make you a fortune."

- Jim Rohn

Revenue & Workforce

How do I write a business plan? How do I create a sales strategy to gain revenue traction? What kind of funding is offered to companies?

Visit the Innovation Hub or the Northwest Texas SBDC for more information about funding, government contracts, and workforce hires.

Information & Contacts







Research Commercialization



Innovation Hub at Research Park

3911 4th St. Lubbock, TX 79415 T: 806-742-0024 Website: <u>innovationhub@ttu.edu</u>

Office of Research Services

2625 Memorial Circle Lubbock, TX 79409 T: 806-742-3884 Website: <u>depts.ttu.edu/research/ors</u>

Office of Research Commercialization

2625 Memorial Circle, Suite 367 T: 806-742-4105 Website: <u>depts.ttu.edu/research/commercialization</u>

Small Business Development Center

5001 W. Loop 289, Lubbock, TX 79414 T: 806-745-1637 Website: <u>lubbocksbdc.org</u>

Appendix

Getting ready to apply for SBIR/STTR

When thinking about applying for an SBIR or STTR grant, producing the actual grant application is only one part of the process that needs to be completed. You should allow at least six weeks ahead of the submission deadline to complete the logistical steps necessary to register your entity with the various databases and government systems required of all government grant applicants.

Current topic areas: https://www.sbir.gov/sbirsearch/topic/current

Online tutorials: https://www.sbir.gov/tutorials

Obtain a data universal numbering system (DUNS) number

The DUNS number is an identifier needed to apply for government funding. The submission process can take one day to one week. You will receive three emails from Dun & Bradstreet: 1) to confirm your submission; 2) to give you the DUNS number; and 3) to provide login information to your company's online account. These emails are commonly caught up in spam filters. To prevent this from happening, add the dnb.com domain to your email whitelist before you begin the application process. You need your DUNS number to complete the CAGE code application.

Note: Occasionally, emails do not arrive. This is usually related to a spam filter issue. If this happens, go to the D&B website and search for your company. You will be able to see whether you are listed yet. If you are, contact customer service to get the DUNS number.*

Obtain a commercial and government entity (CAGE) code

The CAGE code is another identification number needed to do business with the federal government. The submission process can take two weeks to one month. You will receive three emails from the System for Award Management (SAM): 1.) to confirm your IRS taxpayer identification number (TIN or EIN); 2.) to indicate that match validation was successful; and 3.) to give you the CAGE code. This process is lengthy because it deals with multiple entities. SAM processes the basic application but must validate the company's TIN/EIN and DUNS number, and then send the information to the CAGE code office, which has its own review process.

Register company on eRA Commons

eRA Commons is the Electronic Research Administration of the National Institutes of Health (NIH). Access the site at https://public.era.nih.gov/commons/public/login.do. To register your company, click "Register Grantee Organization" on the page above or go to https://public.era.nih.gov/commons/public/login.do. To register your company, click "Register Grantee Organization" on the page above or go to https://public.era.nih.gov/commons/public/login.do. To register your company, click "Register Grantee Organization" on the page above or go to https://public.era.nih.gov/commons/public/registration/registrationInstructions.jsp. The company must have a DUNS number before registering. Companies submitting NIH SBIR/STTR applications must do so through the eRA Application Submission System & Interface For Submission Tracking (ASSIST) system. This registration process allows the company to log in and complete the grant submission.

To register:

1. On the registration page under **Registration Purpose**, select the types of opportunities to which your organization will apply. For SBIR/STTR applications, select **My organization wishes to apply for NIH grants/contracts.**

*The DUNS number is expected to be replaced by a Unique Entity Identifier (UEI) by April 2022. Entities with a DUNS number will automatically receive a UEI.

- 2. Under Institution Information, enter the company's DUNS number.
 - a. The institution name and address automatically populate.
 - **b.** For Closeout Email and NoA Email, enter the founder's email address. If there is more than one founder, choose the founder who is the point-person for the company.
- **3.** Under Accounts Information:
 - a. Under Principal Signing Official, enter the name of the founder who is the point-person for the company.
 - i. Enter their first and last names and title ("Founder").
 - ii. Under Username, enter the company name_SO (for example, PCIV_SO).
 - iii. Enter the phone number for the founder who is the point-person for the company. Enter a number that is checked regularly.
 - iv. Enter the email address for the founder who is the point-person for the company. Enter an email address that is checked regularly.
 - **b.** Under Accounts Administrator, follow the same procedure as for Principal Signing Official, except the Username should be company name_AA.
 - **c.** Once you submit the registration information, you will receive an email confirmation from <u>era-notify@mail.nih.gov</u>. Click on the email link in that message to confirm the information.
 - **d.** Check your email over the next few days for a follow-up email approving the institution registration. Check your junk mail, too. When you receive the approval email, click on the provided link to confirm the company's registration.

Create/link your eRA Commons account for the principal investigator

The next step is to link the company's eRA account with a principal investigator (PI) eRA account. The PI eRA account belongs to the founder or company employee (for example, the CTO or director of R&D) who will be the PI on the SBIR/STTR.

Note: On an SBIR, the PI must be a full-time company employee at the time of award. On an STTR, the PI can be employed by either the Company or the academic institution.

- 1. Log in to the **company name_SO** account at <u>https://public.era.nih.gov/commons/public/login.do</u>.
- 2. On the bar across the top of the page, click the **Admin** tab.
- 3. Click the Accounts tab.
- 4. Click the Account Management tab.
- 5. Search for the PI using the Last Name and First Name fields.
 - **a.** If the PI already has an eRA Commons account (i.e., user ID), their name should populate in the search results. For the appropriate user ID, under the **Action** header in the table, click the **Manage** button.
 - i. Scroll to the Roles section and click the + Add Roles button.
 - ii. From the list, select **PI-Principal Investigator**.
 - iii. In the bottom right corner, click the Add Roles button
 - iv. Save the changes.
 - b. If the PI does not have an eRA Commons account and their name does not appear

in the search results, scroll to the Create New Account button, and click it.

- i. Enter the contact information for the PI and create a User ID (for example, lastname_firstname). Be sure to use the PI's work email address.
- ii. Scroll to the **Roles** section and click the **+ Add Roles** button.
- iii. From the list, select **PI-Principal Investigator**.
- iv. In the bottom right corner, click the Add Roles button
- v. Save the changes.
- 6. Ask the PI to check their email for any confirmation emails from eRA and follow the instructions.

Register on Grants.Gov

Register your company with <u>https://www.grants.gov/register.html</u> submission to the NIH or other federal granting agency such as DoE, USA or DoED. To register the company use this link: <u>https://apply07.grants.gov/apply/register.faces</u>.

To complete the registration page:

- 1. Enter the first and last names of the founder who is the point person for the company.
- 2. Enter the email address for the founder who is the point-person for the company.
- **3.** Enter the phone number for the founder who is the point-person for the company. Enter a number that is checked regularly.
- **4.** Under the **Username**, enter the company name.
- 5. Enter a password.
- 6. Under Grants.gov Username, save the username to Salesforce. Under Grants.gov Password, save the password to Salesforce.
- 7. Uncheck the boxes for Subscribe to Grants.gov Alerts and Subscribe to Grants.gov Newsletters.
- 8. Submit the registration.

Once you have registered the company:

- 1. Log in to Grants.gov using the username and password selected above.
- 2. In the upper righthand corner, click on the My Account button.
- 3. Click on the Manage Profiles tab.
- 4. Click on the Add Profile button.
- 5. Under Profile Type, select Organization Applicant and enter the DUNS number.
- 6. Under Profile Name, enter the company name.
- 7. Under Job Title, enter AOR. The AOR is the authorized organizational representative.

Authorizing the AOR

The Electronic Business Point-of-Contact (EBiz POC) needs to approve Grants. gov profile that was just created. You designated the EBiz POC during the SAM registration. Use the same email address associated with the EBiz POC.

To login as the E-Biz POC, either:

Go to https://apply07.grants.gov/apply/register.faces and click on Log in as EBiz POC

OR

Go to https://apply07.grants.gov/apply/login.faces?userType=applicant&cleanSession=1

To authorize the AOR:

- 1. Under UEI, enter the DUNS number.
 - a. If you don't have the password, click the Forgot **My Password/Unlock My Account** link at the bottom of the page. Enter the DUNS number and EBiz POC email address.
 - **b.** As of May 2020, Grants.gov accepts the DUNS number in place of the UEI number, but this might change soon.
- 2. At the top of the screen, hover over the **Applicants** tab and click **Manage Applicants**.
 - **a.** The page will prompt you to enter a temporary code that was sent to the EBiz POC email address.
 - i. Enter the temporary code as soon as you receive it. It is only valid for a short, though unspecified, amount of time. The website does not accept copied and pasted codes. You must enter the code manually.
- **3.** Once you enter the temporary code, a list of usernames will be shown, including the **company name** username you just created on <u>Grants.gov</u>.
 - b. In the table under the Actions column, click Manage Roles.
 - c. Under Applicant Roles, check Expanded AOR, Standard AOR, and Workspace Manager.
 - **d.** Click Save to allow the company name Grants.gov account to authorize the submission of a grant through the eRA Commons ASSIST portal.
- **4.** Once this step is complete, confirmation emails will be sent notifying the EBiz POC and the company name Grants.gov accountholder of this change.

To find a grant solicitation, go to https://www.sbir.gov/solicitations

Post-Submission

Once you receive confirmation of your submission, be sure to save it in a secure location. Make note of the <u>Grants.gov</u> tracking number on the confirmation email. This number can be used to track the progress of your grant through the NIH process.

To track submission of your grant directly on the ASSIST platform, under the Summary tab, next to **Status**, select the **View Submission Status Details** link. ASSIST Submission Statuses are designated as follows:

- **Submitted:** The grant has been successfully submitted.
- Agency Tracking Number Assigned: Grant submission is in process.
- **Processed:** The grant submission has been processed.

During this post-submission period, you will receive emails alerting you to the progress of the submission. The emails tracking the process will go to the PI on the grant and to the contact person listed on the grant PDF. TTUS suggests listing a person other than the PI as the "person to be contacted about matters regarding this grant." This way, at least two people receive these critical emails.

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Registering your company in SBIR.gov

The company must have an SBIR.gov registration to apply for small business grants (SBIR/ STTR) through the NIH, NSF, or other federal agencies. Click on the following link to register your company: <u>https://www.sbir.gov/registration</u>. Answer the questions as appropriate for the company.

A typical example for a PCIV company pre-investment is provided below:

- 1. Certification Tool
 - a. Type of Firm
 - i. Is your business organized as a for-profit company: YES
 - ii. Is your principal place of business located in the United States: YES
 - b. Ownership and Control
 - i. Is the majority (more than 50%) of your firms' equity (e.g., stock) directly owned and controlled by one of the following:
 - ii. One or more individuals who are citizens or permanent resident alien of the US: CLICK ON THIS OPTION
 - iii. Note that some SBIR/STTR opportunities do not allow companies that have this structure to apply to grants. Check the federal agency's SBIR/STTR solicitation before applying in this case
 - c. Company Size
 - i. Does your business have fewer than 500 employees: YES
- 2. Have you Registered?
 - a. Have you ever applied for funding through the SBIR/STTR program: NO
- 3. DUNS/EIN/Email Check
 - a. Enter the DUNS number.
 - **b.** Enter the EIN number.
 - **c.** Enter the email address associated with the EBiz POC (as described above in the Authorize AOR section).
- 4. SBC Information
 - a. Complete the SBC Information as appropriate for the Company
- 5. Points of Contact
 - a. Complete the Points of Contact. Enter a contact person for every category.
 - **b.** Enter the name of the founder who is the main point of contact in each category, and enter the appropriate email address.
- 6. Complete the registration.
 - **a.** The site will send a login name and password to the email address entered above.
 - **b.** Log into SBIR.gov and reset the password.
 - c. Save the login name and password.
 - d. Download the official SBC registration document.
 - e. Save the file without changing the name (it will be a long string of numbers) for your records.

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