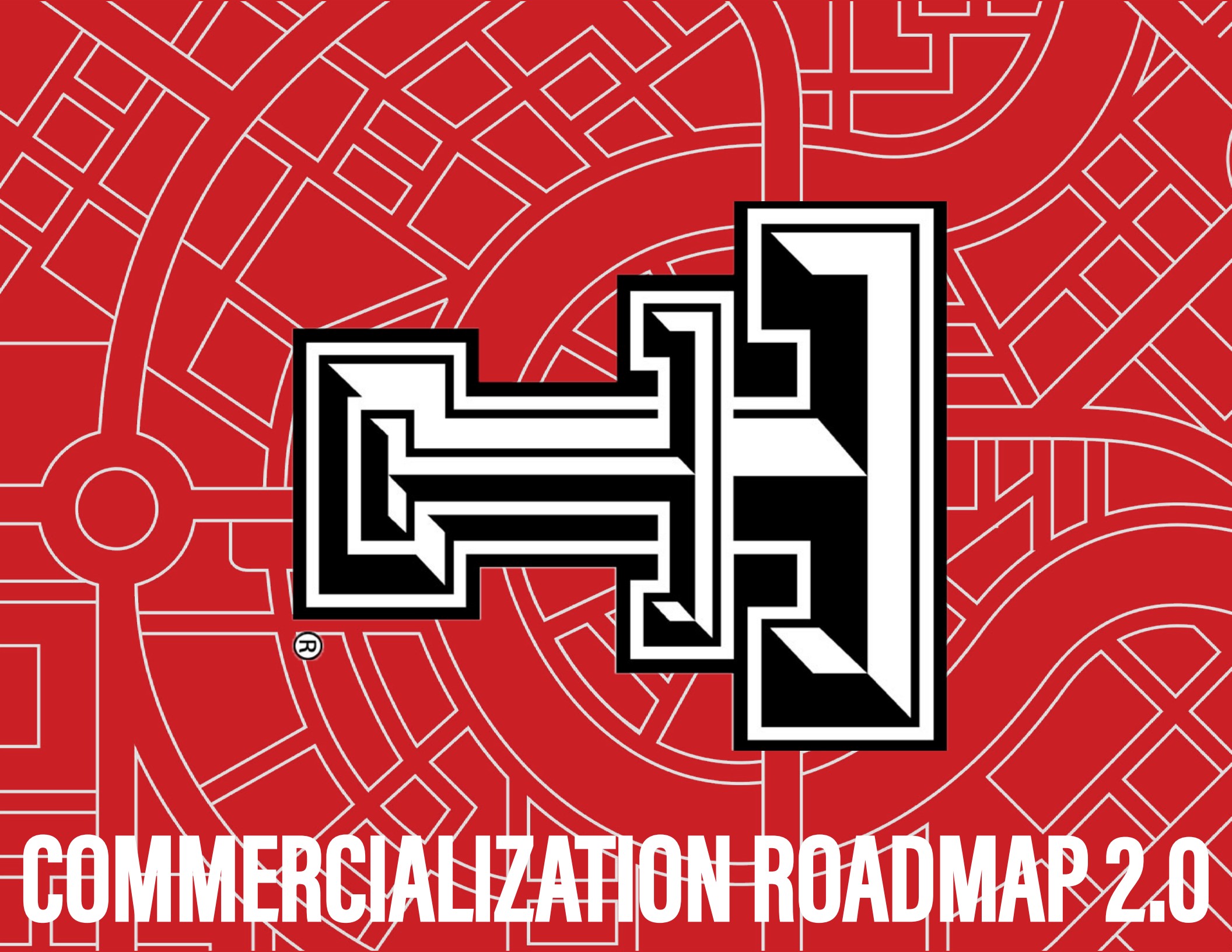
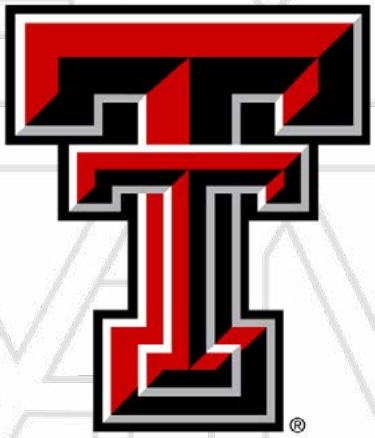


COMMERCIALIZATION ROADMAP 2.0



TEXAS TECH

UNIVERSITY®

THE COMMERCIALIZATION ROADMAP

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

TEXAS TECH

INNOVATION ECOSYSTEM
Commercialization Roadmap

INNOVATION
TOTAL POINTS:

Stage 1: Ideation

Stage 2: Commercialization

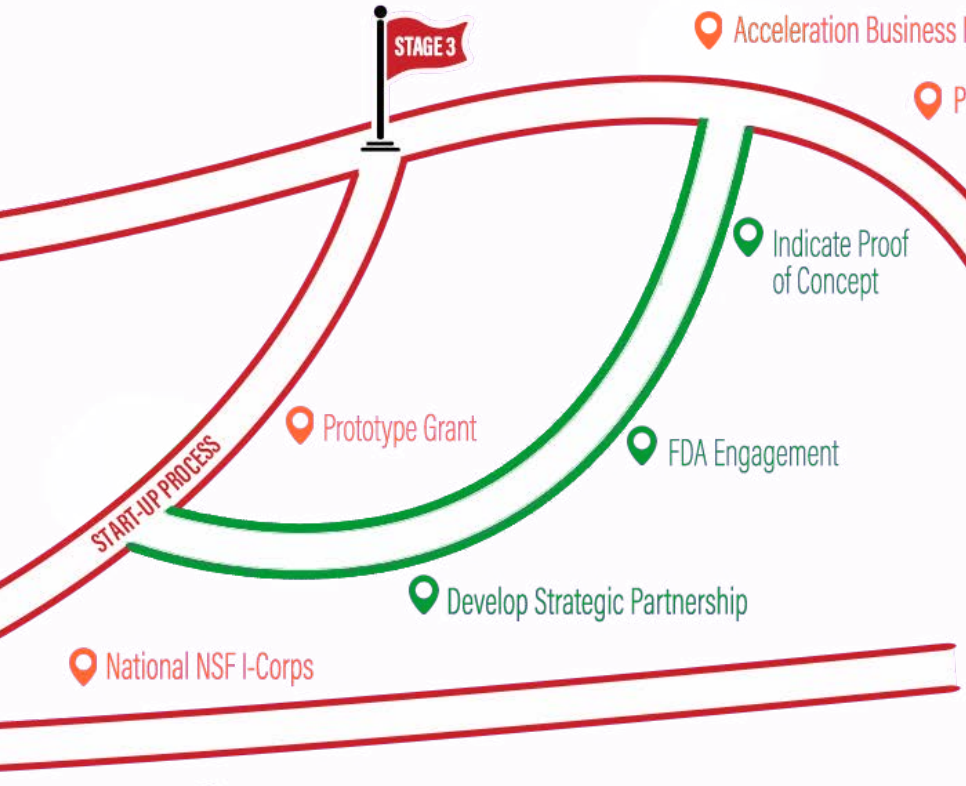
Stage 3: Acceleration

Innovation Hub
New Venture Development & Support

Office of Research Commercialization
Intellectual Property Proctection and Licensing

Small Business Development Center
Consulting, Training, and Research Support for Small Businesses

Office of Research Innovation, TTUHSC
Support Sling Health Innovations



TEXAS TECH IMPACT

Jobs, Technology, Startups, Community, Industry & Investor Engagement, Revenue

Information & Contacts

Innovation Hub at Research Park
New Venture Development & Support

3911 4th St. Lubbock, TX 79415
T: 806-742-0024
Website: innovationhub.ttu.edu

Office of Research Services
Supporting Sponsored Research Projects

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

Office of Research Commercialization
Intellectual Property Protection & Licensing

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

Office of Research Innovation, TTUHSC
Support Sling Health Innovations

3601 4th Street
Lubbock, TX 79430
T: 806-743-1000
Website: ttuhsc.edu/health-professions/default.aspx

Small Business Development Center
Consulting, Training, & Research Support for Small Business

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

Innovation Assessment

1. Do you have an innovation?

A. ☐ Yes, I have a working prototype.

B. ☐ Yes, I have a prototype drawing.

C. ☐ 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.

C. ☐ No, I do not have trademarks, copyrights, patents, or any 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. ☐ 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. ☐ No, I do not have scientific research.

5. Have you legally established your business?

A. ☐ Yes, I have established a legal business entity.

B. ☐ Yes, I have a DBA (Doing Business As) only.

C. ☐ 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?

A. ☐ Yes, private capital investors (e.g., angel investors, seed funding).

B. ☐ Yes, private investors (e.g., personal, family, and friends).

C. ☐ 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. ☐ 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. ☐ No, I do not have prior startup experience.

11. Is your innovation focused on pharmaceutical or digital health technology?

A. ☐ Yes, my innovation focused on pharmaceutical technology.

B. ☐ Yes, my innovation focused on digital health technology.

C. ☐ No, my innovation does not focus on either technology listed above.

12. Have you negotiated an industry partnership?

A. ☐ Yes, we have negotiated an industry partnership.

B. ☐ We comunicated with Industry about a partnership, but do not have a partnership.

C. ☐ No, we have not communicated with Industry concerning an industry partnership.

Add up your points using the key below:

TOTAL POINTS:

A=3 Points	**0-16** **Stage 1:** Ideation
B=2 Points	**17-26** **Stage 2:** Commercialization
C=1 Point	**27-32** **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, and Kathryn Dankesreiter, Marketing Coordinator. 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 ORI, TTUHSC, ORC leadership team and TTU Office of General Counsel in reviewing this resource.

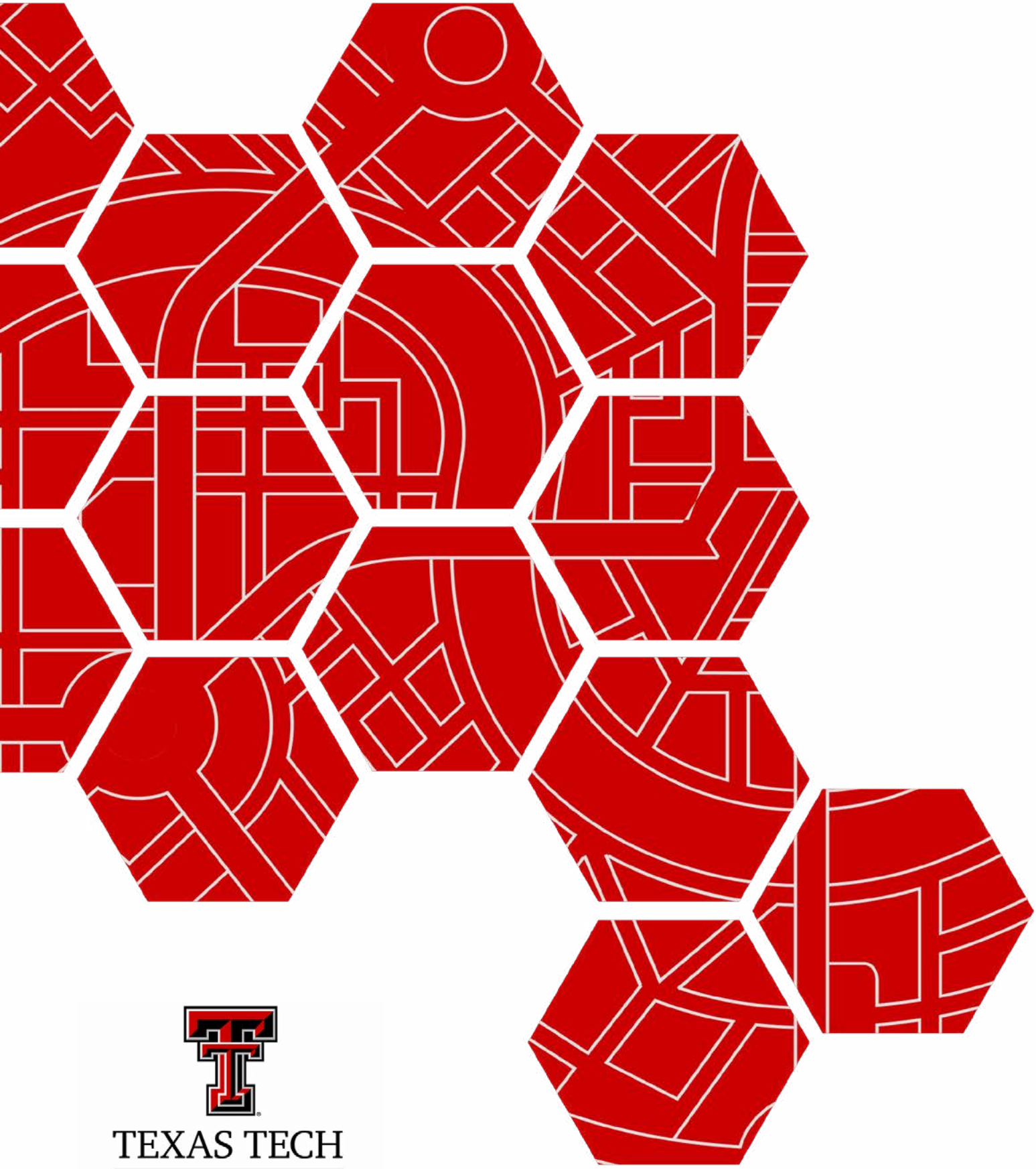
References

https://pci.upenn.edu/commercialization-guide/

https://www.uspto.gov

https://www.sbir.gov

Contents



TEXAS TECH
UNIVERSITY.

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, commercial industry, and others. 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.

Different innovation ecosystems can be distinguished from one another in terms of the way their innovations are translated from idea-to-impact. For example, healthcare technologies can be categorized as one or more of the following: device, diagnostics, pharmaceuticals, or digital health. Device and diagnostic innovations typically translate in a fashion similar to other STEM technologies, where the inventors rely upon federal funding models to validate their customers, technologies and market, culminating in investor support for launching a start-up and building a successful company. Conversely, pharmaceutical innovations often focus on commercialization processes in collaboration with targeted future industry partners who will fund different Proof-of-Concept phases that ultimately lead to continued partnership or license and exit strategies.

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, SBIR/STTR training, and SBA loan programs.
- 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.
- Assessing Texas Tech intellectual property and research discoveries, and marketing certain IP to facilitate industry relationships.

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

STEP 2:
Complete Innovation Assessment

STEP 3:
Identify initial destination/ introductions; engagement meetings

SUCCESS STORIES
CIPDAR

CIPDAR Team

Dr. Shin Ye Kim, Founder, CTO, and CEO
Hannah Yoo, Founder, CMO, and CFO
Nguyen Nguyen, Founder and COO

Psychology Researcher Developing Culturally Informed Pain Diagnosis Technology

by Abby Stone

When Shin Ye Kim came from South Korea to the U.S. 12 years ago as a master's student in psychology, she expected to work closely with people who have mental health issues. But while working toward her doctorate several years later, she began providing individual and group psychotherapy to hundreds of chronic pain patients in a Wisconsin clinic.

"By working with patients and their families and seeing how powerful psychological interventions are for those with chronic pain, I was amazed by the deep connection between mind and body." explained Kim, a licensed psychologist and assistant professor in the Texas Tech University Department of Psychological Sciences.

Language barriers further exacerbate these issues, a lesson Kim understood deeply. As a student, she often felt frustrated she couldn't use the equivalent descriptive words in English that she would have in Korean – some had no exact translation, and others simply didn't exist in English.

A decade later, Kim's experiences culminated in the creation of Culturally Informed Pain Diagnosis and Relief (CIPDAR), an innovative technology that provides multilingual, multimodal and multidimensional pain assessment and management for linguistically and culturally diverse patients.

"Our passion for helping chronic pain patients unites our team and motivates our work," Kim said. "We are interested in developing technology that provides patients and providers a pathway to more effective pain communication, which will help facilitate more accurate diagnoses and better patient outcomes. Our technology aims to overcome language and cultural barriers that can impede the diagnostic and treatment process of chronic pain."

Now, Kim and two counseling psychology doctoral students, Hannah Yoo and Nguyen Nguyen, are working to bring CIPDAR to fruition, with help from the Innovation Hub at Research Park as part of the fifth cohort in the Texas Tech Accelerator Program.

With Kim as the technical lead and Yoo and Nguyen as co-entrepreneurial leads, the CIPDAR team went through the regional NSF I-Corps program in fall 2020.

"Regional NSF I-Corps was an enriching learning opportunity that challenged many of our traditional ways of thinking as researchers," Kim said. "The program tasked us to look beyond the focused goals of our research lab and start thinking about the real-world applicability of behavioral health psychology."

During regional NSF I-Corps, Yoo and Nguyen investigated the commercial landscape, helping the team gain critical customer insights.

Together, they analyzed information gathered from those interviews to further refine the product and its business concept. At the same time, Kim submitted the invention disclosure to the Texas Tech Office of Research Commercialization. After being evaluated for patentability, the concept was deemed a novel approach to pain diagnosis, and one for which a strong market exists.

At the end of three weeks, they presented their results.

"Most insights we heard from potential customers validated our understanding of the core problem: Chronic pain is inherently difficult to communicate, treat and diagnosis, and it is even more challenging for limited English-proficient patients," Kim said.

After integrating their results from the regional NSF I-Corps program, the CIPDAR team applied for the NSF I-Corps national program and was quickly accepted $50,000 in funding to support further discovery.

"As a team, we are incredibly grateful to have this opportunity and engage in interdisciplinary work, leveraging research outside the laboratory," Kim said. "Above all else, we would all like to thank everyone who has been and continues to be so helpful and encouraging. We appreciate the tremendous support from Innovation Hub faculty and staff."

The Hub

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 www.innovationhub.ttu.edu.

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.

Red Raider Startup

Red Raider Startup, an exciting three-day 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.

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.

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.

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.

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 dti.ttu.edu.

SUCCESS STORIES
FiberTect™

FiberTect™ Team

Seshadri Ramkumar, Inventor of FiberTect™

Amit Kapoor, President of First Line Technology

Corey Collings, First Line Technology

*Fabric manufactured by Hobbs Bonded Fibers - Waco.

Decontamination Wipe From Texas Tech Could Help Toxic Chemical Cleanup Efforts

by Glenys Young

A decontamination wipe invented by a Texas Tech University researcher to clean up toxic agents also could clean up bodily fluids contaminated with the coronavirus.

FiberTect™ is a three-layer, nonwoven wipe that features an activated carbon core sandwiched between absorbent top and bottom layers.

"It is widely used as the primary dry decontamination method in hospitals and ambulances," said Corey Collings, a training specialist for First Line Technology, which markets FiberTect™. "Hospitals use it in bulk and in rolls, and ambulances use it in a kit called the FastGrab to do immediate decontamination of patients contaminated with a wide variety of substances."

FiberTect™ was invented by Seshadri Ramkumar, a professor of chemical countermeasures and advanced materials in the Texas Tech Department of Environmental Toxicology. He says the wipe's structure is effective in containing bodily fluids – like saliva and mucus – through which viruses could be transmitted. Its activated carbon also can absorb particles transmitted in vapor phase through the air.

As a wipe or mitt, FiberTect™ holds great potential for cleaning in settings where transmission of the COVID-19 virus, also known as the novel coronavirus, is a paramount concern.

"It can be used to clean wet surfaces contaminated with bodily fluids," Ramkumar said. "Highly porous carbon in the structure can capture and trap the vapors and aerosols in which microbes are contained. The wipe structure is flexible and can take the shape of the objects to be cleaned. The three-ply structure without glue helps this effective cleaning."

Ramkumar was recently featured in the Hub Hustle blog on another nonwoven product he invented, Towelie.

FiberTect™ previously has been used successfully by the U.S. military to decontaminate both personnel and equipment. Nonwoven wipe technologies developed by Dr. Ramkumar's team find applications in oil spill clean-up and absorbing dangerous chemical substances, including fentanyl.

"The advantage of FiberTect™ is that it has multiple uses," said Amit Kapoor, president and CEO of First Line Technology. "Many departments have bought into decontamination technology solely because of the fentanyl epidemic. However, once they have the equipment, like FiberTect™, they find that it is effective at removing a broad range of dangerous substances. Some examples include OC spray, bodily fluids, acids, and other unknown materials. Because it is so easy to store and use, it has gained widespread acceptance among public safety agencies."

Its development and testing were sponsored by the U.S. Department of Homeland Security and managed by the Technical Support Working Group, Office of the Assistant Secretary of Defense for Special Operations/ Low-Intensity Conflict in the U.S. Department of Defense. Lawrence Livermore National Laboratory conducted product testing. FiberTect™ proved superior in all testing results against 30 comparable products for decontaminating against toxic chemicals.

"I'm really thankful that Texas Tech University took a chance on launching research in the area of nonwovens when I came here 22 years ago," Ramkumar says. "The investment in research pays off, as shown with this and other technologies that have evolved at Texas Tech. One application often piggybacks on another. I'm very pleased that Texas Tech University is doing its part in being of help in times of need. To all researchers and entrepreneurs, I say creativity is the need of the hour. Crises demand innovation, even if it is an invention of incremental development. The Innovation Hub at Texas Tech plays a vital role in that," he says.

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 the customer segment and product-market fit is essential for inventors in prioritizing an innovation's market entry through either growing a business or exit with licensing out their invention to industry for product launch. The following commercialization programs are free and open to all students, faculty, and community members. Stay updated on program application deadlines at www.innovationub.ttu.edu.

National Science Foundation Innovation Corps.

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.

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/

NSF I-Corps official webpage

The National Science Foundation's Innovation Corps (I-Corps™) program uses experiential education to help researchers gain valuable insight into entrepreneurship, starting a business or industry requirements and challenges. I-Corps enables the transformation of invention to impact. The curriculum integrates scientific inquiry and industrial discovery in an inclusive, data-driven culture driven by rigor, relevance, and evidence. Through I-Corps training, researchers can reduce the time to translate a promising idea from the laboratory to the marketplace. NSF is developing and nurturing a national innovation network to guide scientific research toward the development of solutions to benefit society. For more information, visit https://www.nsf.gov/news/special_reports/i-corps/

Steve Blank's Lean LaunchPad

This Lean LaunchPad is built around the business model / customer development / agile development solution stack. Students start by mapping their initial assumptions (their business model). Each week they test these hypotheses with customers and partners outside the classroom (using customer development), then use iterative and incremental development (agile development) to build Minimal Viable Products. For more information, visit https://steveblank.com/category/lean-launchpad/

NIH I-Corps Site

The I-Corps at NIH program is focused on educating researchers and technologists on how to translate technologies from the lab into the marketplace. The program provides three-member project teams with access to instruction and mentoring in order to accelerate the translation of technologies currently being developed with NIH and CDC SBIR and STTR funding. For more information, visit https://grants.nih.gov/grants/guide/notice-files/NOT-CA-20-106.html

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. For more information, visit https://www.depts.ttu.edu/research/research-park/prototype-build/prototype.php

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
- [ ] Complete your TTU/TTUHSC Conflict of Interest and Commitment Disclosure (see page 46)
- [ ] Update your TTU/TTUHSC Conflict Management Plan (CMP) if you are a faculty member.

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.

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.

Industry Partnerships

Selected Industries respond to early stage innovators by PARTNERING. Industry partners give small innovators leverage. Industry partners can sponsor (see page 39) financial support to innovators for funding milestone-driven bench, pre-clinical and clinical proof-of-concept experiments that aim to validate the technology, clinical applicability and market. Meeting milestones can lead to start-up launch and continued partnership or exit and licensing.

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 innovationhub.ttu.edu/ie/

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 seed-stage 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. innovationhub.ttu.edu/ie/

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 high-opportunity 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/

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


AMERICA'S
SBDC
Texas Tech University

Revenue & Workforce

Small Business Development Center

Northwest Texas SBDC is a part of America's SBDC's nationwide network of nearly 1,000 Small Business Development Centers (SBDCs) – the most comprehensive small business assistance network in the United States and its territories.

SBDCs are hosted by leading universities, colleges, state economic development agencies, and private partners, and funded in part by the United States Congress through a partnership with the U.S. Small Business Administration. America's SBDC at Lubbock is hosted by Texas Tech University to provide no-cost business consulting and low-cost training to new and existing businesses.

How do I write a business plan?

The SBDCs offers free or low-cost workshops which include business topics such as how to start a business, understanding the finances of a business, marketing, Texas state sales tax, and a variety of others. The classes are held in a relaxed atmosphere which encourages interaction and gives the attendees the opportunity to have their individual questions addressed.

https://www.lubbocksbdc.org/services

How do I create a marketing strategy?

It is critical that a business owner understands the demographics, market and industry forecasts. The SBDCs have access to top industry standard reports, statistics, and databases, that can be beneficial for growing existing or future businesses. Their consultants can gather and analyze the information and present it to you in an easy to understand format, all at no cost to you.

What kind of consulting is offered to companies?

The SBDCs offer confidential business consulting at no cost to our clients. Their knowledgeable and experienced team will help you define your goals, operations, and objectives. We can help you develop a business plan, identify sources of capital, or determine what the next step may be - whether you are on the road to becoming an entrepreneur or already own a business and are ready to meet the next challenge.

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

Anyone Can Be An Entrepreneur

"I think if anyone is interested in growing a business and brand, they should definitely do it! The world needs more entrepreneurs and founders; and if you don't think you have enough experience, no one does."

- Danielle West, Founder of East Lubbock Art House

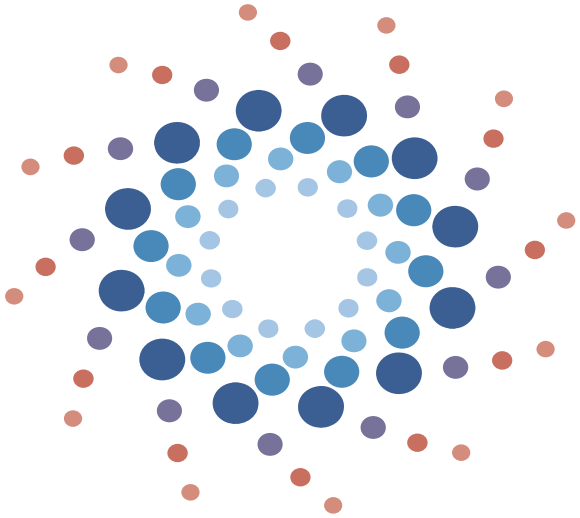
What is SBIR/STTR?

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 for-profit 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

sbir.gov

Key differences between SBIR/STTR programs

STTR differs from SBIR in three important aspects:

1. 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.
2. 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.
3. STTR program allows the principal investigator to be primarily employed by the partnering research institution.

SBIR/STTR hint

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 sbir.gov and grants.gov 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

SBIR/STTR Application 8-Step Process

Step 1: Any time before the deadline

- Review what past proposals the agency funds
- Determine company eligibility
- Get pre-submission feedback from the SBIR/STTR Program Director (optional)
- Register with SAM.gov and other specific company registrations needed (required)

Step 2: Identify solicitation topic

- https://www.zynsys.com/sbir/

Step 3: 90 days before the deadline

- Review the solicitation

Step 4: 60 days before the deadline

- Register your company
- Start your application

Step 5: Deadline

- Applications due by 5:00 pm in your local time zone

Step 6: 1-3 months after the deadline

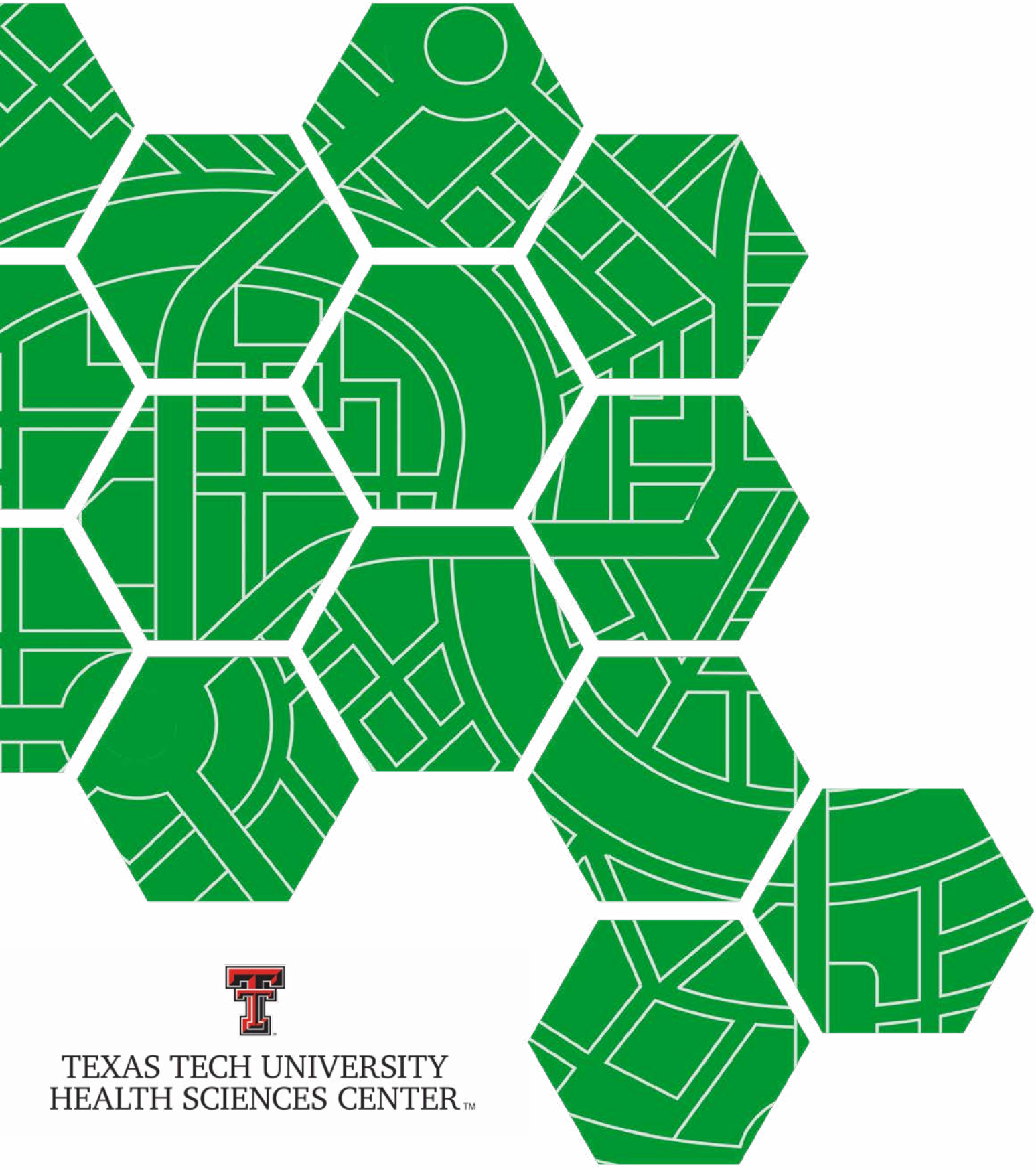
- Applications undergo panel and merit reviews

Step 7: 4-6 months after the deadline

- Agency will notify you whether your proposal is accepted or declined

Step 8: 5-6 months after the deadline

- If proposal is accepted, funding will be disbursed



TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™

Health Science Innovations

Formation of a Health Science Innovation Industry Partner

Health Science innovations, especially those in the pharmaceutical or digital health domains, can often require several millions of dollars for proof-of-concept (POC) and validation, as well as preliminary regulatory compliance, incubation and licensing prior to launch into the market. Moreover, the innovators in this category prefer to complete these processes in collaboration with targeted future industry partners who will fund the different POC phases. Many health science industry leaders such as Merck, Pfizer, Roche, Johnson & Johnson (JLabs), Biome, and UnitedHealthcare, have created virtually integrated pharma, biotech and digital health innovation partnerships with university inventors and startups. These partnerships leverage university inventiveness to increase the speed and agility of delivering innovation to the public, while reducing the overhead that was previously encountered with the same industries' traditional in-house, fully integrated R&D processes.

Commercializing health science innovations can be a complex process involving many steps that must be synchronized in order to lead to a LEAN LAUNCH. Often Innovators ask when they should plan on engaging in the different commercialization activities. Because health science commercialization can require extensive time and costs, the innovation team can benefit from taking the steps in a timely fashion in order to avoid loss of momentum, stalls, and burnout. Please refer to page 67 to locate the Appendix 3: Health Science Research Commercialization Gantt Chart to view an example of milestones timeline.

The Gantt Chart illustrates the milestones, many of which can be achieved through programming at the TTU Innovation Hub. Milestones should be cohesive with each phase of POC ideation, commercialization, acceleration, grant funding, establishing industry partnerships and FDA Regulatory Evaluation and Approval. Because of the complex milestones that many health science innovations require for completing commercialization to reach public impact, attention to this synchrony will help the innovators reach their commercialization goals in a timely fashion.

Once all of the POC phases are successful and milestones are met, which can lead to a variety of different arrangements that include the following:

1. Asset Acquisition: The industry partner purchases the LLC from the inventor.^
2. Licensing: Industry licenses the technology from the University^
3. Industry Equity Investment: The Industry invests in the asset to support formation and launch of a collaborative NewCo.
4. Full partnership between the start-up and the industry group for further product development and future related projects.

Initiate Proof of Concept

Intiate Proof-of-Concept Program

Health Science Innovation often requires several Proof-Of-Concept (POC) experimental phases to validate the new technology. (Appendix 3: Milestone 1). Often Industry Partners will work to secure funding for the innovator completing the different POC Phases (Appendix 3: Milestone 6).

Step 1 is a Bench POC, which could include any of the following:

- Bench laboratory experiments (In-Vitro; for example, testing cell responses to a new compound)
- Modeling experiments (for example, mathematical prediction of tissue treatment response)
- Cadaveric tissue response (ex-vivo; for example, examining treatment response of cadaveric tissue)
- Case simulation experiments (for example, hypothetical case response using a new program or app)

Step 2 is a pre-clinical POC (In-Vivo). This could involve any of the following:

- Laboratory animal response to a treatment (for example, pharma impact on lab animal physiology)
- Test User group response (for example, using a pre-selected user group to validate a new App)

Step 3 is a Clinical Proof of Concept where actual patients are exposed to the new technology in order to see if the technology creates the response that it claims to create.

Step 4 is a Clinical Trial (randomized if available) that compares the new technology with an existing industry reference standard.

Conduct "Customer" Discovery

While the patient is the ultimate technology user, the health science customer is often embodied in different aspects of the relevant industry ecosystem. Innovators need to take the necessary preliminary steps to identify the points, value propositions and relationships needed for successful industry partnerships. Innovators need to understand these elements for the ultimate user (the patient) in context with the potential industry partner (or "customer." for example, members of a pharmaceutical company). Recommendations to innovators for customer discovery:

- Complete regional (and potentially NSF) I-Corps (Appendix 3: Milestone 3)
- Investigate the potential industry partner's current portfolio
- Identify other groups that the potential partner is considering for partnership
- Identify the current potential partnership opportunity

Conduct Competition Discovery

In order to successfully secure a partnership, the innovator needs to not only understand the impact the technology has on the patient, but they also need to: (1) understand the potential unique impact of technology in the respective ecosystem; and (2) understand potential competitors. Key Considerations:

- Identify the competition
- Understand how their technology is different from the competition
- Clarify if there is a marketplace for the technology innovation

Execute Company Development and IP Protection

As previously discussed, health science innovators can form a start-up company that serves as a "vehicle" for industry partnership. The health science innovator's commitment to a startup can increase the partners' confidence that the start-up company will complete the different POC steps (Appendix, Milestone 1), thus reducing the investment risk for the partner. To learn about forming the start-up company, the innovator can refer to page 12 that reviews the steps for starting a business. Additionally, if the start-up company uses a technology that is owned by Texas Tech University System, then the innovator should follow the instructions on executing a license agreement found on page 41-42. Finally, the innovator can participate in the TTU Accelerator Program to Lean Launch the start-up company's formation (Appendix 3, Milestone 7).

Initiate FDA Agreement

The health science innovator is advised to investigate if the innovation requires FDA regulation (Appendix 3: Milestone 8). Regulation spans the pre-market, pre-launch, and post-market periods across the technology life-cycle. (See page 63: Engaging with the FDA).

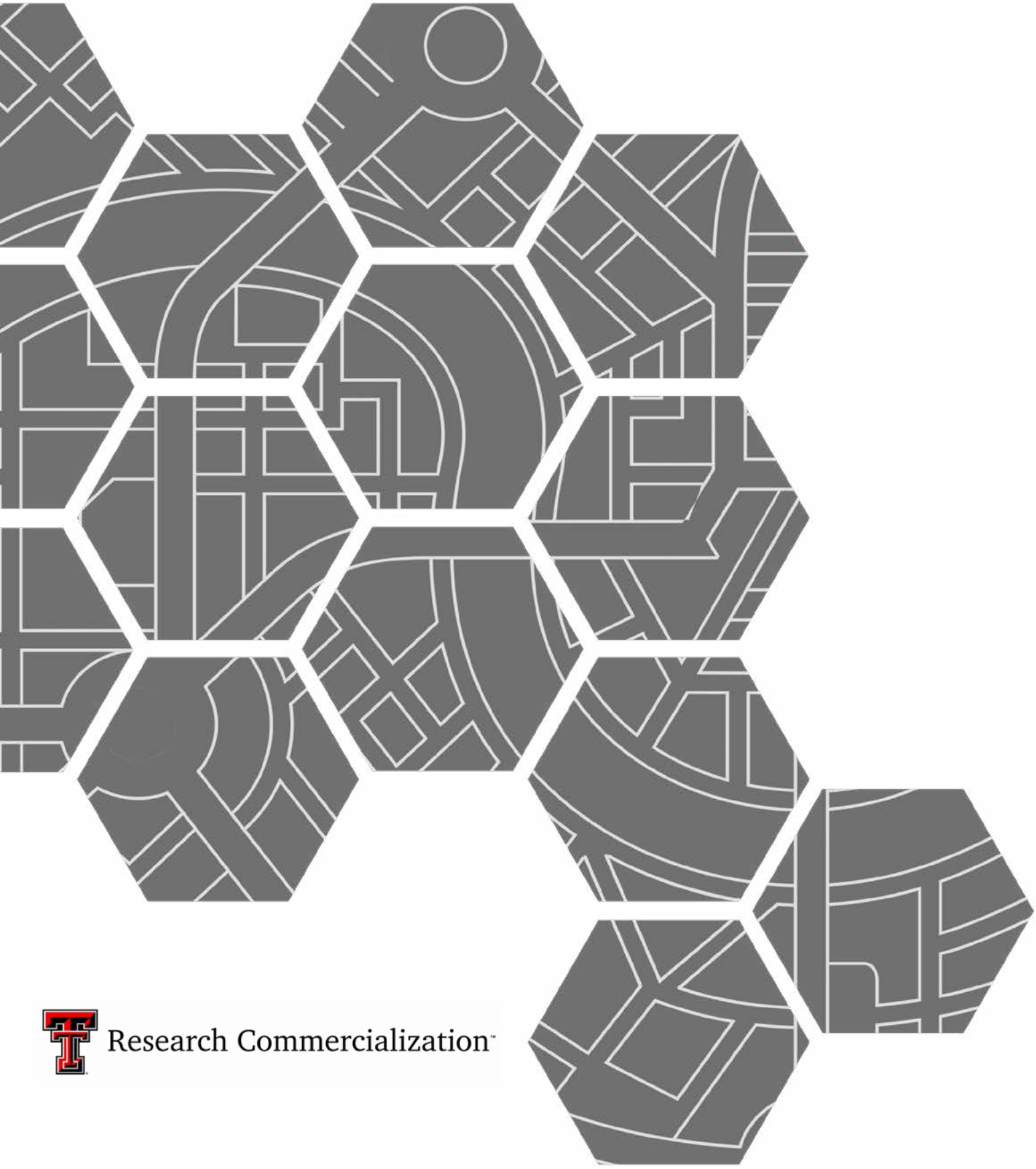
Initiate a Negotiative Process

Interaction with a potential industry partner will include a series of steps that transform an interaction into a relationship. Once the inventor and potential partner agree that the relationship is worth exploring, then the industry will initiate essential steps to formalize the partnership. If the company is based on technology owned by the TTU System, then the negotiations are conducted between the industry and the TTU System General Counsel (see below for specifics). University of California at San Francisco (UCSF) developed the following steps that de-risk the industry resource investment and lead to approved partnership at TTUHSC:

- The industry will screen the inventor to check for red flags
- The industry will evaluate the innovation on technical and commercial level
- Both sides will exercise technical, commercial and contract Negotiation Due Diligence*
- Both sides will discuss the potential Partnership's details*
- Both sides will negotiate Non-Binding Term Sheet (NBTS; or Letter of Intent)*
- Both sides will craft Confidence Disclosure Agreement (CDA)**
- Both sides will negotiate the Data Sharing Agreement**
- Both sides will negotiate a Contract, Professional Services or Consulting Agreement*

*Negotiated with the TTUHSC Office of the TTUS General Counsel and
TTUS Office of Research Commercialization (ORC)
**If funded, it requires evaluation by TTUHSC Office of Sponsored Programs

[1] Campbell Alliance – Dealmakers' Intentions – 2015 Survey of licensing decisions makers


Research Commercialization™

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.

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

How do I submit an invention disclosure?

For TTUS faculty, staff, and students, an invention disclosure can be completed through the online Invention Disclosure Portal at https://ttu.wellspringsoftware.net/ via your eRaider login credentials.

Alternatively, an editable pdf of the Invention Disclosure form can be downloaded from the ORC website: https://www.depts.ttu.edu/research/commercialization/inventors/downloads/TTU-ORC-Editable-Invention-Disclosure-Form.pdf

Please complete as much of the form as possible, then submit it, along with any accompanying information, to the ORC 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.

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

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. https://www.uspto.gov

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 (www.uspto.gov).

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.

© Copyright

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. *

*Content provided by Penn Center for Innovation.

Role of the Office of Research Commercialization

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 subscription-based technology scouting platform that can be reviewed by potential licensees looking for technology solutions. You can view your posted technologies at technologies.texastech.edu. 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. *

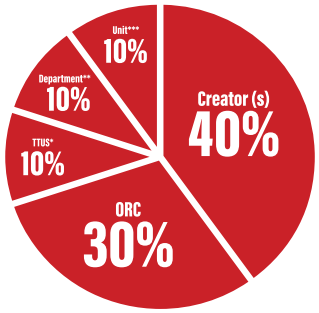
*Content provided by Penn Center for Innovation.

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).

Licensing Revenues



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

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.

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.

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 cash-strapped 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.

Requirements

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.

1. Execute Confidentiality Agreement between TTUS and company and discuss technology and licensing plan in detail.
2. Execute Option Agreement if company (or team) is still in validation stage of technology.
3. Exchange and negotiate Term Sheet based on company intent and business plan.
4. Agree to terms and draft full exclusive or non-exclusive License Agreement.
5. 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 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.

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.

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 http://www.depts.ttu.edu/research/ors.

Safeguarding Student Inventions

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 co-created 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.

FAQs for research and discoveries

What rights of use 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

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 https://www.depts.ttu.edu/opmanual/OP10.20.php

Why do I need a Conflict Management Plan?

A faculty member will complete a Conflict Management Plan (CMP) which is reviewed and approved by the COI committee to assess project manageability and recommend revisions based on best practices.

Student Conflict

Student Assistants

Students paid by the university or working directly with a faculty member are subject to disclosure requirements. Faculty are encouraged to consult the conflict office at their institution to necessarily include students that may be involved in their research.

Student Intellectual Property

As discussed in the TTUS Patent Policy, student IP is not owned by the TTUS unless the student is receiving funding for their work (including graduate stipends), working with a faculty member, or using significant institution resources. See the section on invention disclosure requirements with the ORC when IP is owned by TTUS.

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 do I need to Know about Financial Disclosure?

Overview of Financial Disclosure and Financial Conflict of Interest (fCOI): What is this?

Texas Tech Operating Procedure 74.17 provides the university's official regulations and procedures regarding financial conflicts of interest. These procedures are in place to ensure compliance with federal regulations and, more importantly, to ensure that the university's vibrant research community conducts itself with openness and transparency. The procedures also serve to protect the credibility and integrity of the institution and its people, ensuring that sponsored activities are not compromised (or perceived to be so) in any way.

Who must disclose?

All employees who plan to act as investigators are required to disclose significant business and financial interests, including those of their spouses and dependent relatives or household members, by October 1st of each year, and on an annual basis thereafter. If an employee has no such interests, a disclosure indicating so is still required. An investigator is a PI, co-PI, and any other person at Texas Tech, or Texas Tech subgrantees, contractors, or collaborators, who is responsible for the design, conduct, or reporting of research or educational activities that are funded or proposed for funding by an external entity.

How do I disclose?

Only investigators with sponsored research projects are required to disclose. All disclosure forms are located at https://ttu.my.irbmanager.com/. This is a secure link that requires eRaider authentication for access. Once you have disclosed, each annual update thereafter will automatically prepopulate the previous year's information for your convenience.

PHS (NIH) Research Funded Investigators

The Public Health Service requires all investigators submitting PHS proposals or currently receiving PHS support to take two steps: complete required training, and file PHS-specific financial disclosure information. The PHS guidelines also define an "investigator" as the project director, principal investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding. Under these guidelines, your collaborators or consultants may be considered "investigators" for PHS compliance purposes. For PHS-specific procedures, please see the back of this sheet.

What if I have questions?

If at any time you have questions, encounter problems with the online disclosure system, or need assistance with FCOI matters, please contact Marisol Alonzo, FCOI Administrator (marisol.alonzo@ttu.edu).

PHS Disclosure Procedures

PHS FCOI- compliance procedures require two steps: training and disclosure.

Training

Investigators will need to complete training before submitting new PHS proposals OR receiving new awards (including non-competitive renewal awards). Renewal of training is also required every 4 years. Two training options are available (either of which can be completed in around 30 minutes). Trainees will need to complete one of the two available training options:

Conflict of Interest CITI Training (preferred) – https://citiprogram.org

Current Users:

1. Click "Add a course or update your learner groups for Texas Tech University."
2. On the next screen, select "Yes" to Question 2 – "Would you like to take the Conflict of Interest mini-course?
3. On the next screen, click the title of the course under "Courses" to begin the course.

New Users:

1. Click "Register Here" and complete the registration steps.
2. On the next screen, select "Yes" to Question 2 – "Would you like to take the Conflict of Interest mini-course?"
3. On the next screen, click the title of the course under "Courses" to begin the course.

At the successful conclusion of the mini-course, you will be presented with the option to print a transcript. Submit a PDF copy of this transcript to Marisol Alonzo at marisol.alonzo@ttu.edu to document completion of the requirement.

Disclosure

Investigators also need to disclose business or financial interests before submitting a PHS proposal, and annually thereafter. To disclose for PHS purposes, log into the FCOI Online System using the link on the front of this page and indicate where appropriate your status as a current or prospective PHS awardee.

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/OP32.07.php

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.

Texas Tech University System patent policy

TTUS' patent policy is governed by Chapter 10 of the TTUS Regents' Rules which can be found at http://www.texastech.edu/board-of-regents/regents-rules/chapter-10-intellectual-property-rights.pdf. 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.

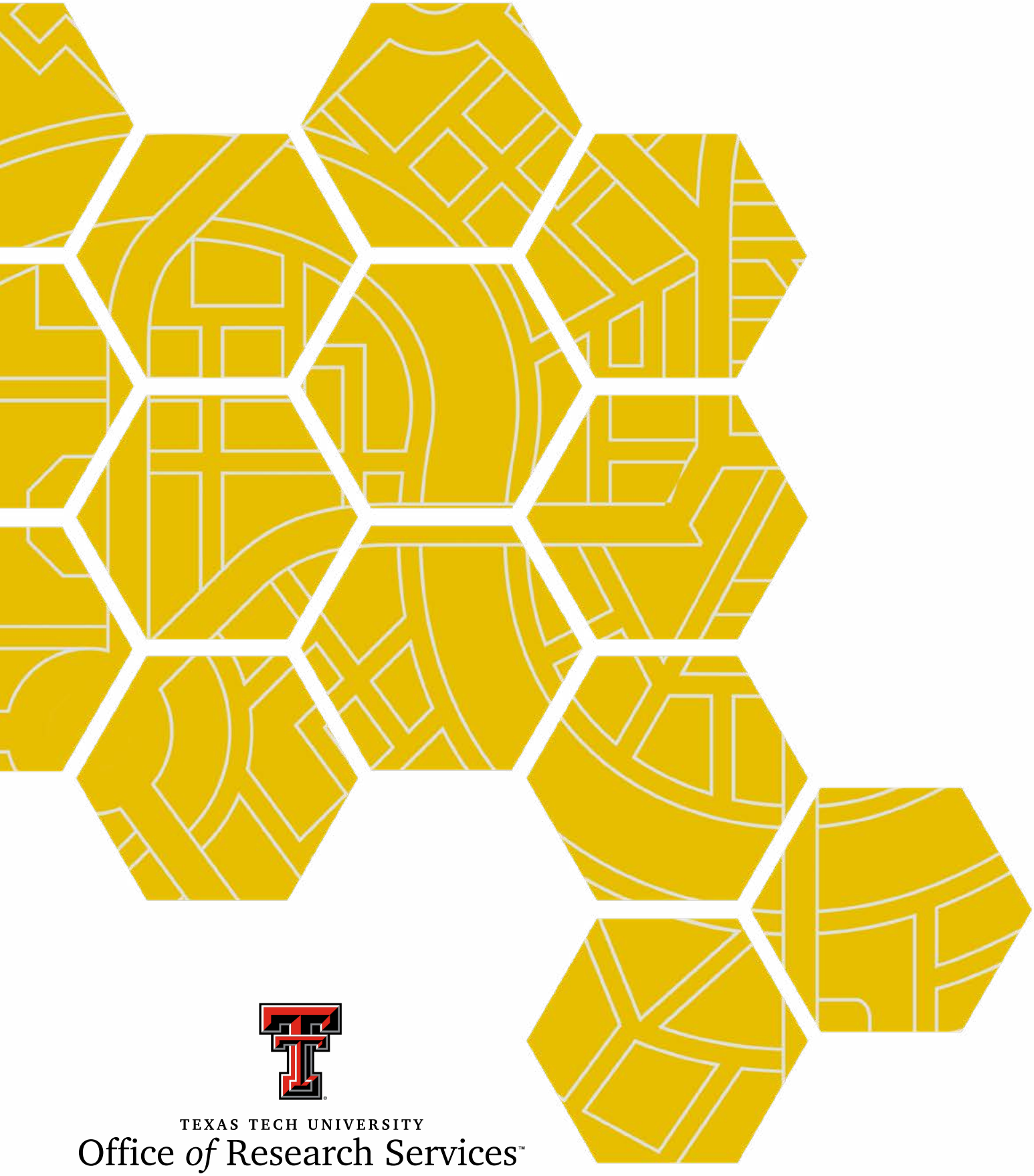
MISSION

(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.



TEXAS TECH UNIVERSITY
Office *of* Research Services™

Sponsored Research Activities

Confidentiality agreements are a necessary part of SRAs and protect you and the institution from jeopardizing your research and TTUS patent rights. Confidentiality agreements should be in place before any external party visits your lab or has detailed discussions about your commercial work. It is also recommended that even TTU students within your lab (especially undergraduate volunteers), execute confidentiality agreements with the institution.

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:** call (806) 742-2011 or vist the Office of Research Services (ORS) website
- **Texas Tech University Health Sciences Center:** call (806) 743-1000
  or visit the Office of Sponsored Programs website
- **Texas Tech University Health Sciences Center-El Paso:** call (915) 215-8000
  or visit the Office of Sponsored Programs website
- **Angelo State University:** call (800) 946-8627 or visit the Office of Sponsored Projects website

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 corporate, 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.

Sponsored Project Lifecycle

The ORS supports the mission of Texas Tech by providing administrative and management services for sponsored projects. Sponsored projects include grants, contracts, and cooperative agreements–from both the public and private sectors–which support research, instructional and service projects. The Sponsored Project Lifecycle below illustrates the necessary steps sponsored projects should take and how to ensure safety and research compliance.

Finding Funding

For funding and grant opportunities, review "How do I fund a startup?" on pg. 18 or visit the Innovation Hub website.

Proposal Development

While investigators are expected to write their own proposals and prepare their own submissions, the Office of Research & Innovation (OR&I) does provide assistance and resources to make the process more efficient and effective. The Office of Research Services (ORS) is the primary contact for pre-award needs and is the office that will submit a final proposal to a funding agency.

Proposal Review and Submission

Proposals for extramural support for research, training, or other activities to be conducted by Texas Tech faculty, staff and students are required to be submitted through the TTU Office of Research Services. Texas Tech uses the Cayuse Electronic Research Administration System to submit proposals. Contact appropriate TTUS office if the proposal is not submitted by TTU.

Award Process

The Office of Research Services (ORS) is the central point of contact for agency grant or contract officers regarding administrative matters both during award negotiation and throughout the project. Once an award or amendment has been reviewed and signed by ORS and the Sponsor, award and budget information is provided to the Office of Accounting Services (AS). All post award services and inquiries will be handled through AS unless a change in award is required.

Award Management and Closeout

Accounting Services supports the research mission of TTU by providing training and education, financial administration, compliance, and other research support services to faculty and staff. AS is responsible for the post-award administration and oversight of the university's sponsored projects.

Safety and Research Compliance

Texas Tech is dedicated to the safe and ethical conduct of research, scholarship and creative activity. Funding agencies may require prior approval for human or animal research, information about environmental health and safety, disclosure of financial conflict of interest. For more information, visit the Office of Research Services website at https://www.depts.ttu.edu/research/ors/.

Sponsored Research FAQs

I am a student and conducting research as an employee of a small business in collaboration with TTUS faculty. Is it possible to use TTUS facilities?

Yes, it is possible to use TTUS facilities in collaboration with TTUS faculty. Since you are conducting the project not as a TTUS student, but as an employee or owner of another entity (company or sole proprietor), a Facility Use Agreement (FUA) will need to be drafted and executed through the appropriate System Sponsored Projects Office. The FUA will include terms and conditions for the use of specific space at TTUS facilities. Including, but not limited to, compensation for the use of space and equipment, liability, insurance, and confidentiality. The use of TTUS facilities will be subject to the TTUS educational and research programs. Prior to working on a project at a TTUS facility in your capacity as a company employee, you and the TTUS faculty member should contact the appropriate System Sponsored Projects Office listed on page 44 to negotiate the details of an FUA.

My small business was just awarded an SBIR/STTR from a federal agency and TTUS is a subcontractor on the award. Now what?

If you receive an award from a federal agency and a TTUS university is a subawardee/subcontractor on the award, notify the TTUS faculty member who is the principal investigator on the subaward/subcontract and the appropriate System Sponsored Projects Office. TTUS universities handle sponsored research and the agreements associated with them on a regular basis and can help draft an appropriate subaward/subcontract agreement or review one if the company wishes to draft an agreement. But remember, the company and the TTUS university are separate entities and must review and execute the subaward/subcontract separately and for each entity's own interests.

I am a student of a TTUS university and received an Accelerator grant for a start up company. What is the TTUS university's role now? Is there still a faculty/student relationship if my mentor is a TTUS faculty member?

If you receive an award through one of the grants or awards listed on Page 18 in the capacity as an employee or owner of a startup company, you are considered a separate entity from the TTUS university. The dealings you have with the TTUS university once you apply for and receive one of these awards will be as a separate legal entity. Any agreements you enter into for this award/grant, will be between you, in your capacity as a small business owner, and the TTUS university or Texas Tech Research Park, Inc. As the business owner, you have certain fiduciary duties and responsibilities to the business that are separate from your duties and responsibilities as a student.

Pursuit of the American Dream

"Unquestionably, I have had to make sacrifices to dedicate substantial time and effort co-creating this company, but it is all in the pursuit of an important problem that I am passionate about, and a solution our company can deliver that will hopefully improve healthcare globally, one step at a time."

- Travis Reiss, CEO

SUCCESS STORIES

Surgic

Surgic Team

Travis Reiss, CEO, Founder

Paul Egan, CTO, TTU Dept. of Mechanical Engineering

Kyle Feen, COO

Christopher Ackerman, CMO

Arham Siddiqui, CFO

Surgic's Anatomy: The Next Big Innovation in Surgical Training Tools

by Kathryn Dankesreiter

Surgic's surgical training device is the next big innovation in medical education. Travis Reiss, co-founder and CEO of Surgic, explains that "Surgic aims to substantially improve the educational toolkit available to medical residents".

Surgic provides hospitals and surgeons the opportunity to practice procedures without the high cost of traditional cadavers. The company's first product, which they aim to release in summer 2022, "will simulate and provide a training platform for midline laparotomies exclusively, with more products focused on other critical surgical procedures to come."

Two founders, including Travis Reiss, formed their initial team in Dr. Paul Egan's Mechanical Engineering Capstone. Dr. Egan is one of the Innovation Hub's esteemed 2020-2021 Faculty Ambassadors.

Prior to pursuing his dream, Reiss began his college career at the Edward E. Whitacre Jr. College of Engineering. "I often felt that I was right where I was meant to be, amongst my engineering student peers, as we worked to solve problems together, step-by-step and with precision, with all necessary information clearly described. The way of the engineer."

It wasn't until Dr. Egan's class that Reiss's entrepreneurial spirit was ignited. The capstone course integrated entrepreneurship and engineering design. "It really motivated me early on and helped me recognize that I could pursue entrepreneurial endeavors as an engineer." The project Reiss started in class with co-founder Kyle Fenn. Dr. Egan's background in healthcare, led the two mechanical engineers to Dr. Catherine Ronaghan, a surgeon and professor at the TTUHSC.

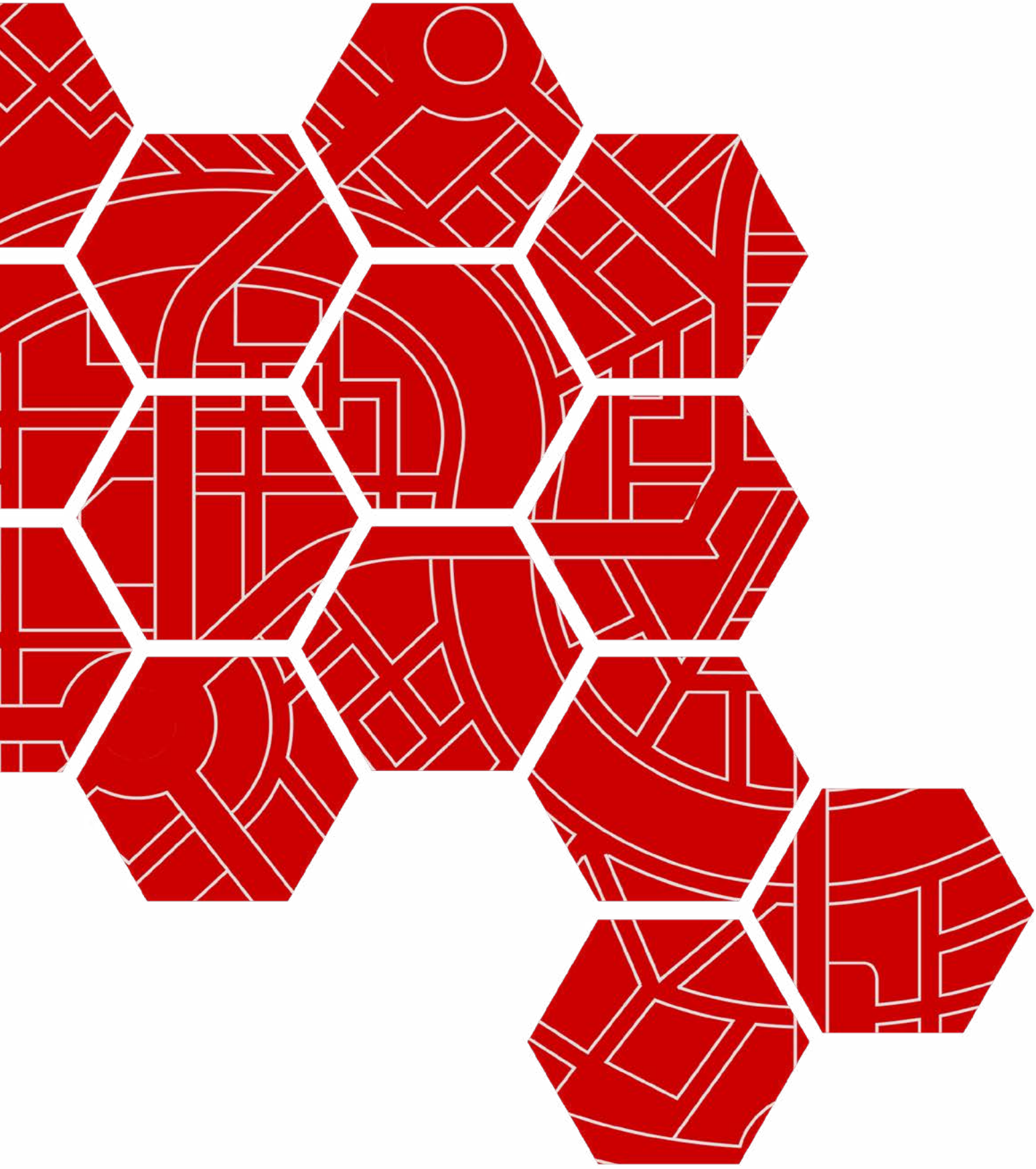
After several meetings Dr. Ronaghan to discuss the limitations of current surgical training devices, Reiss and Fenn launched the project through NSF I-Corps. "NSF I-Corps was hugely instrumental in pushing my group's capstone project from the classroom and into prospective startup landscape. Following huge validation and encouragement during customer discovery, Kyle and I were brimming with excitement and ready to take this to the next level." Surgic was formed on February 2nd, 2021.

Travis Reiss, Dr. Paul Egan, and Kyle Fenn, with the guidance of Dr. Catherine Ronaghan, set their sights on Innovation Hub programs including the Presidents' Innovation Award and TTU Accelerator.

As Surgic began to grow through the team's involvement in Innovation Hub programs, the team recognized they were missing a few key players. The mechanical engineers onboarded Arham Siddiqui, a medical student and MBA, as Surgic's CFO. Shortly after that, the team connected with Chris Ackerman, an engineering consultant and TTU alumni. Surgic welcomed Ackerman as their CMO.

In fall 2020, Surgic won the TTUHSC's President's $25,000 award. Spurred by the momentum of the win, the team competed in the 2021 Discoveries to Impact TTU Accelerator program and was accepted into the one-year program.

Equipped with a diverse team of mechanical engineers and business and medical professionals, Surgic aims to launch their minimum viable product (MVP) by next year.



Appendix 1

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/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.

* Contents provided by SBIR.

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 era-notify@mail.nih.gov. 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 https://public.era.nih.gov/commons/public/login.do.
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

*Contents provided by Penn Center for Innovation.

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

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**

*Contents provided by SBIR.

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 Grants.gov.
    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 Grants.gov 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.

*Contents provided by Penn Center for Innovation.

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: https://www.sbir.gov/registration. 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.

*Contents provided by SBIR.

Appendix 2

Engaging with the FDA

The Health Science Innovator is encouraged to investigate if the intended healthcare USE of the innovation requires FDA regulation in early phases of the innovation lifecycle. It is never too early to begin learning about FDA regulation for a Health Science innovation use.

The FDA is regulatory, not advisory, in nature. The agency regulates the intended use of the technology for diagnosing, curing, alleviating, treating, or preventing disease. Regulation spans the pre-market, pre-launch, and post-market phases across the technology life cycle. The pre-market phase regulation focuses on technology attributes, manufacturing and labelling for safety, quality, and accuracy. The pre-launch phase requires FDA regulation of innovation registration and advertising practices, while the post-market phase regulation addresses after-sale obligations, clinical performance monitoring, problems alerts, and risk management. Interaction with the FDA requires the innovator to navigate a minimum of [3] FDA filings to complete the FDA approval process.

The inventor must work to determine if the intended use of an innovation requires FDA regulation. The innovator is reminded that Health Science innovations are characterized as Device, Diagnostics, Pharmaceuticals and or Digital Health applications. The FDA regulates the use of innovations from all categories. Digital Health is the fastest growing of these, presenting with the greatest regulatory challenges aimed at medically applied digital applications. Technology using standalone software, mobile medical applications, and digital data systems represent rapidly accelerating innovation growth, creating frequent iterations of FDA regulatory policies. An innovator is required to stay current with the changes to optimize compliance.

Medical Device Classification

The FDA offers information regarding medical device approval process.[1] The Inventor will determine device classification for an innovation technology's use as Class I, Class II, or Class III. Class I is considered LOW Risk, subjecting the technology use to general controls. These are often exempt from pre-market FDA notification, or clearance through substantive equivalence determination. Class II is considered MODERATE risk, which is subject to both general and special controls. Pre-market notification is generally required for Class II devices,[2] and may be a Direct De Novo Classification Request.[3] Class III devices are considered HIGH risk, which requires general controls and premarket approval.[4]

*Contents provided by the Office of Research Innovation.

[1] https://www.fda.gov/medical-devices

[2] https://www.fda.gov/media/82395/download

[3] https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request

[4] https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma

FDA Medical Device Approval Process

The following milestones must be achieved before certain Medical Devices can be sold.[5]

1. The investigator searches the FDA classification database to identify the medical device classification. If classification cannot be determined, the inventor should use 513(g) process to request classification.
2. Innovative Class II and Class III Devices will likely require a clinical study (High quality randomized clinical trial, or RCT) or Systematic Review of existing RCTs.[6] Inventors can seek FDA Pre-Submission feedback for their innovation.
3. A 510K Pre-Market Notification (PMN) application and fee payment must be completed and submitted for Class II devices.[7]
4. Pre-Market Approval (PMA) application and fee payment must be completed and submitted for Class III devices.[8]
5. Class II and III devices require an FDA facility inspection of all major suppliers involved in innovation design and production.
6. The FDA issues a 510K clearance letter or PMA and posts them online for all Class II and Class III devices, respectively.[9]
7. Once registered, the FDA may perform random inspections after device registration.
8. An inventor appoints an FDA US Agent representative as a local point-of-contact.
9. Once approved, the Device is listed, company registered, and fees paid on the FDA website, using the FURLS system.[10]

After these milestones are reached the device can be sold in the US. The authorization remains until changes are made to the Device design or intended use.[5]

*Contents provided by the Office of Research Innovation.

[5]Rao, G. Overview of FDA Regulations. Presented at the 1st Annual UCSF Entrepreneurship for Life Science/Healthcare Startups: Master Class Direct from Silicon Valley. Virtual, Fall, 2020.

[6]Van Norman, GA. Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices, JACC: Basic to Translational Science, 2016; 277-288.

[7]https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks

[8]https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

[9]https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances

[10]https://www.access.fda.gov/

FDA Pharmaceutical Regulation and Approval

The FDA regulates the use of pharmaceutical technology. The following guidelines are associated with new drug development and FDA approval.

1. New drug development guidelines are provided at the FDA Drug Development website. [11]
2. Pharmaceutical innovators must submit a New Drug Application (NDA) to the FDA. The NDA ensures drug safety, effectiveness, accurate labelling, and manufacturing integrity / quality. NDA guidelines are posted with the FDA.[12]
3. The new drug development lifecycle follows commercialization steps, where innovators collaborate with targeted Industry Partners.
4. Industry Partners fund different Proof-of-Concept (POC) phases that ultimately lead to continued partnership or license / exit strategies (see page 27: Formation of a Health Science Innovation Development Partnership).
5. During the POC phases, the physician conducting the POCs submits an Investigational New Drug (IND) Application.[13]
6. The IND allows Industry Partners to attain exemption from FDA to ship investigational drugs across state lines. Once IND is attained, the technology becomes a new drug that is subject to regulation.
7. IND submission requirements: (1) Data from animal pharmacology and toxicology studies; (2) Clinical protocols; (3) Investigator qualifications; (4) Manufacturing information; (5) Informed Consent from subjects; (6) IRB approval evidence; (7) evidence of regulatory adherence; (8) labelling mock-up.
8. The FDA pharmaceutical review process is under continuous evolution, where contemporary models are being adopted to modernize the process.[14]

Once clinical POC experiments have been completed, the FDA will examine all submitted data to decide on drug approval status. The FDA monitors the technology's safety once the product is made available to the public.

*Contents provided by the Office of Research Innovation.

[11] https://www.fda.gov/drugs/development-approval-process-drugs/how-drugs-are-developed-and-approved.

[12] https://www.fda.gov/drugs/types-applications/new-drug-application-nda

[13] https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application

[14] Hearns-Stewart RM, Farley J, Lee KJ, Connelly S, Lowy N, Stein P, Bugin K. The Integrated Review: FDA Modernizes the Review of New Drug Marketing Applications. Ther Innov Regul Sci. 2021 May;55(3):467-472. doi: 10.1007/s43441-020-00240-1. Epub 2020 Nov 24. Erratum in: Ther Innov Regul Sci. 2020 Dec 16;: PMID: 33236259.

FDA Digital Health Regulation and Approval

Where Diagnostic Innovations fall under the Device milestones (above), Digital Health technologies share tenets from both Device milestones and pharmaceutical guidelines. While many of the metrics and milestones for successful Digital Health FDA approval align with other applications (eg...Device), the space is ever changing and innovators are encouraged to stay current with FDA Digital Health perspectives.[15]

Digital Health approval criteria depend on the classification of each specific application. Digital Health innovations are classified as: software as a medical device (SaMD), advanced analytics, artificial intelligence, cloud-based medical technology, cybersecurity, medical device interoperability, medical device data system (MDDS), mobile medical app (MMA), wireless medical devices, and or novel digital health. Links to further reading are available on the FDA Medical Device Interoperability link.[16]

Digital Health regulatory guidance is under continuous evolutionary change that is influenced by contemporary rulings, including Section 3060(b) of the 21st Century Cures Act.[17] Links to specific guidance documents can be found on the Guidance with Digital Health Content website.[18]

*Contents provided by the Office of Research Innovation.

[15] https://www.fda.gov/medical-devices/digital-health-center-excellence

[16] https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-criteria

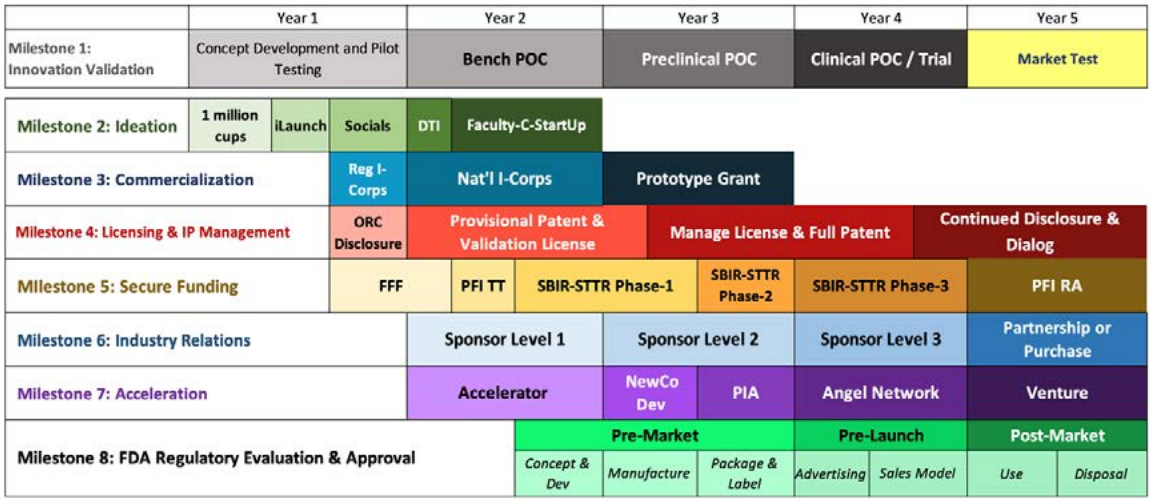
[17] https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-reports

[18] https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content

Appendix 3

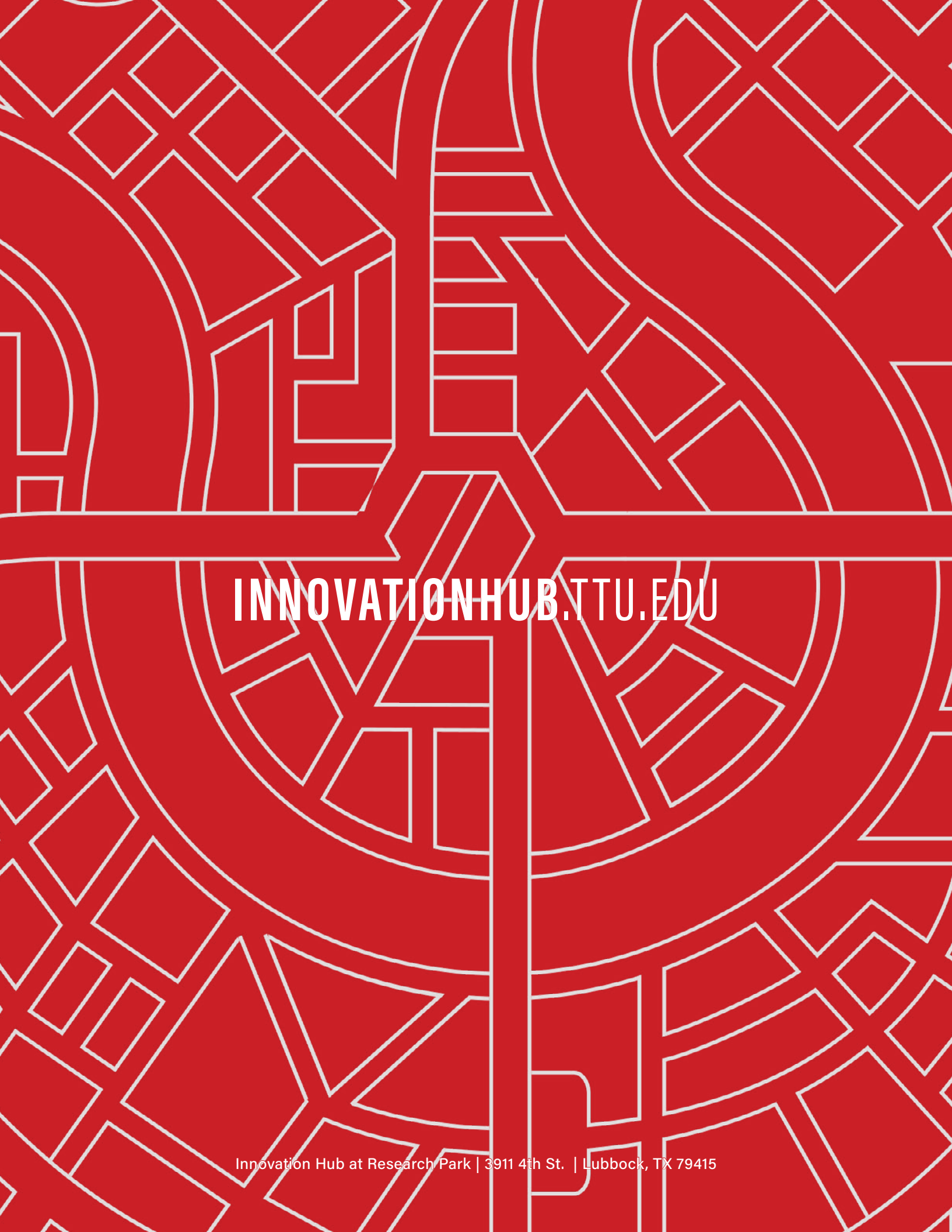
Health Science Research Commercilization Gantt Chart

The Health Science Innovator can refer to the following Gannt Chart that illustrates an efficient approach to achieving the milestones that help launch or exit/license a health science innovation in the TTU System.



Legend: POC = Proof-Of-Concept; DTI = Discoveries-to-Impact (Conference at TTU); ICorps = Innovation Corps for Customer Discovery; PIA = Presidents Innovation Award; NewCo Dev = Start-Up Development; ORC = TTU Office of Research Commercialization; Pub = Publication-these should be evaluated by ORC; FFF = Friends, Family and Fools; PFI TT = Partnerships for Innovation Phase 1: Technology Transfer; SBIR = Small Business Innovation Research; STTR = Small-Business Technology Transfer Research; Partnerships for Innovation Phase 2: Research Alliance; FDA = Food & Drug Administration

Time frames posted at the top are speculative. The timeframe can be higher, depending on the complexity of the technology, commercialization steps and validation processes.



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