THE OHIO STATE UNIVERSITY

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

OHIO STATE DESIGN

Overview Information

Opportunity Title	**2021 Request for Proposals (RFP) for Development of Medical Devices through a CCTS Medical Device Co-Design Studio**, a one-semester, project-based experiential learning course on translational innovation for graduate students which marries the core principles of design with best customer- or stakeholder-centric venture practice using creativity and imagination to achieve breakthrough innovations that solve real problems and create value for patients and people who are ultimate beneficiaries.
Opportunity Purpose	The Co-Design Studio course aims to accelerate proof-of-concept and business case of up to 3 university owned, early-stage medical device technologies to ensure that the device is useful, usable, feasible, desirable and viable and to bring them closer to the market. The 3 life science projects will be selected through this competitive process. Determining interest of the target market or market validation is critical to business success of a new medical device startup and scaling a business is all about profitability. There can no profits without revenue and there can be no revenue without customers. Most importantly, there can be no customers if the needs, strengths, aspirations of the customers of the proposed medical device care about are not fully explored, understood and addressed at the front end. Device customers may include diverse stakeholders such as patients, community members, healthcare providers/staff or hospital administrators.

Key Dates

Release Date	December 23, 2020
Application Due Date	January 12, 2021, midnight
Notice of Selection of Devices	January 15, 2021
Pitch presentations By Inventors	January 25, 2021
Co-Design Workshop 1	February 15, 2021
Co-Design Workshop 2	March 8, 2021
Co-Design Workshop 3	March 29, 2021
Final Presentation Date	April 19, 2021

Table of Contents

Section I. Opportunity Description

Purpose

CCTS is funded by the National Institutes of Health (NIH) National Center for Advancing Translational Science and aims to deliver high-quality high-impact research supporting team science and generation of preliminary data to enable researchers to successfully compete for extramural funding. The goal of NIH NCATS is to transform translational science to get more treatments and interventions to more patients more quickly. The Translational Innovation Program of the Ohio State CCTS seeks medical device proposals consistent with the Center's mission at any "stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public" as described in NIH NCATS' Translational` Science Spectrum. The Translational Innovation Program of the Center for Clinical & Translational Science (CCTS) is committed to transform processes to optimize how faculty, staff and students are inventing, advancing and commercializing medical devices to address unmet clinical needs. Federally funded research drives nearly one-third of U.S. patents— a number that has increased steadily since the 1970s. Through a multi-stakeholder partnership along with key program partners, in partnership with the Corporate Engagement Office and Nationwide Children's Hospital's Office of Technology Commercialization , we aim to grow a community of support across disciplines and colleges to surround each innovator with a groundbreaking idea at our campuses at each commercially relevant step. Breakthroughs tend to occur at the intersection of disciplines within a creative problem solving framework of innovation. Additionally, as providers within a broader entrepreneurial ecosystem, we are working closely with our partners to create a robust network of resources for our researchers and inventors. This includes our shared mission to create a thriving regional innovation cluster to grow the economic impact of innovation in Ohio through launch of startups from The Ohio State University and Nationwide Children's Hospital. One aspect of this mission is the nurturing of entrepreneurial capacities and mindsets through entrepreneurship education that is fully integrated into university curricula to make it accessible to all students as innovative business ideas may arise from technical, scientific or creative studies.

Key Terminology

Translation - The process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

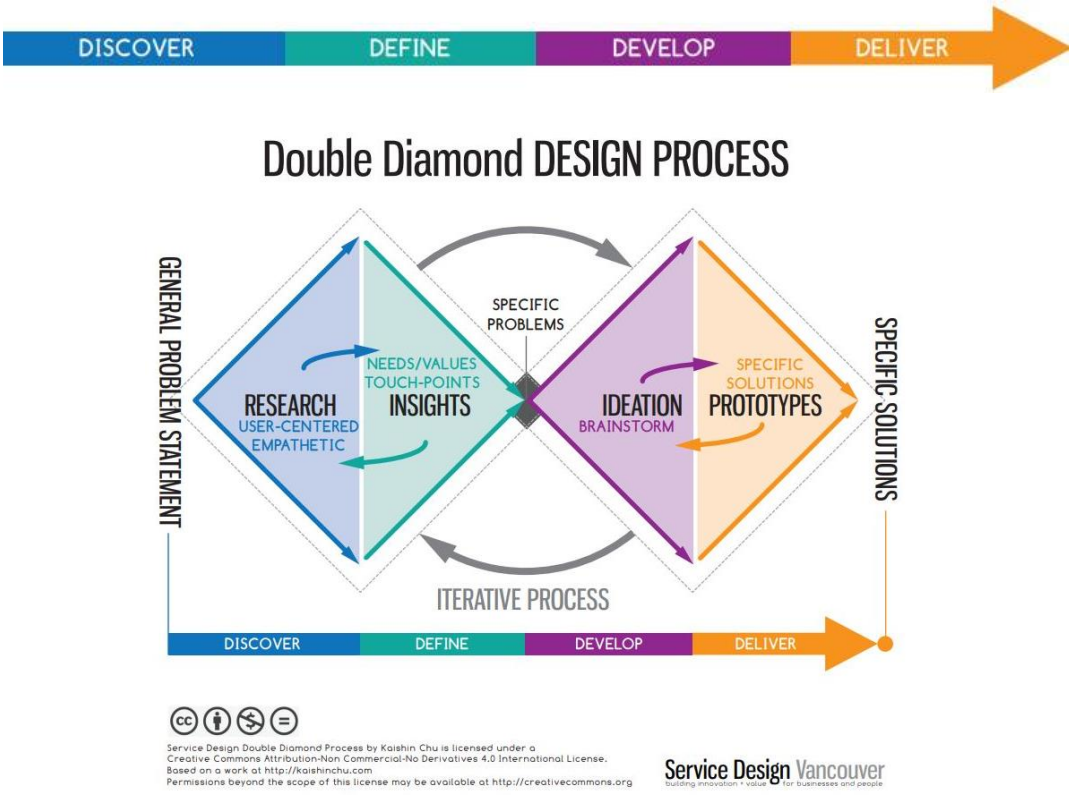
Translational Science - The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. Translational science for benefiting human health requires the convergence of a diverse array of disciplines, including biology, chemistry, informatics, computer science, engineering, medicine and public health, into a united effort to uncover the scientific and operational principles leading to efficient and effective translation. A fundamental distinguishing characteristic of a translational scientist is multiplex outlook, intentionally advancing translation across disciplines by breaking down silos to collectively advance the development of a medical or health intervention.

Translational Science Spectrum – **Develop, Demonstrate & Disseminate** - The translational science spectrum represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. The spectrum is not linear or unidirectional; each stage builds upon and informs the others. At all stages of the spectrum, NIH NCATS develops new approaches, demonstrates their usefulness and disseminates the findings. Patient involvement is a critical feature of all stages in translation.

Translational Innovation through Intellectual Property (IP) –The process of driving breakthrough science and innovative ideas that benefit individual and public health out of the university into practice through commercialization of intellectual property – "laboratories to market". **Commercialization** means "*converting or moving "technology" into a profit making position"* and **technology** refers to know-how, techniques, patented or otherwise proprietary processes, materials, equipment, systems, etc. Commercialization is the process of moving a technology or innovative concept from the idea stage to the marketplace. In other words; **technology commercialization** is commonly defined as the process of creating a product that is suitable for a particular market at an affordable price that fulfills the demand of the market. In general terms, **intellectual property** is any product or creation of the human intellect that the law protects from unauthorized use by others, creating a limited monopoly in the protected property. Intellectual property embodies unique work reflecting someone's creativity and is all around us, manifested through miracle drugs, computer games, films, and cars. The main areas of intellectual property law that innovators use to protect their ideas are: patent, copyright, trademark, and trade secrets. Although generating new knowledge through academic research is a noble endeavor, IP is the lifeblood of the US economy and represents the genius of America to the world. IP not only provides incentives to inventors, strong IP protection and enforcement are essential to creating jobs and promoting economic prosperity, opening new markets for U.S. goods and services; and fostering investment in innovation and development. In academia, IP may come from a student, staff or a seasoned researcher. However, the decision to commercialize a technology is often made by the

academic inventor without a complete understanding of the processes and requirements that will ensure success. Successful translation of innovative research/ideas to market requires a vigorous entrepreneurial spirit, a readiness to cross boundaries and ability to think differently. Health innovators need the right mix of 3 C's - culture, coordination of resources, and capital - that nurtures and accelerates innovation– including innovation in drugs, devices, services, processes, and care delivery.

Design Thinking for Translation of Innovation– **Discover, Define, Develop, Deliver** - *Design Thinking* (DT) is an adaptable methodological innovation that is particularly useful for early stage innovation projects such as medical device development. Just like translational science, DT emphasizes interdisciplinary collaboration for creative, human-centered problem solving for maximizing real-world impact. The world renowned 'Double Diamond' process created by The British Design Council, describes modes of thinking that designers use, originating from Industrial Design. The Double Diamond shown below is a structured design approach to tackle challenges in four phases, mapping the divergent and convergent stages of a design process utilizing analytical and creative approaches in a systematic, iterative manner with diverse stakeholders to identify problems, develop solutions, seek feedback throughout and iteratively improve them similar to the emphasis on involving patients at all stages of TS spectrum. The two diamonds in this framework of innovation depict the process for designing the right product and then designing it the right way.



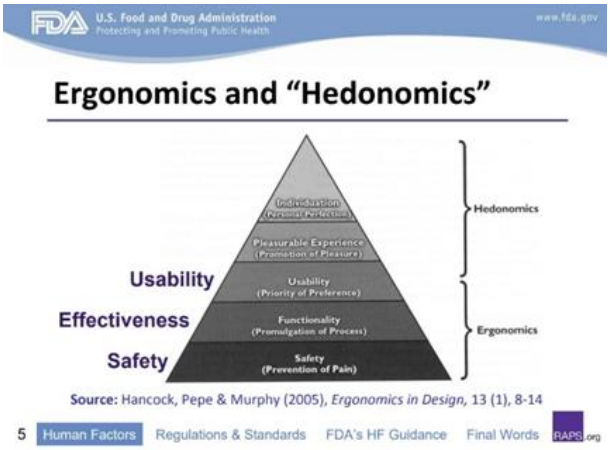
In the Discover/Research phase, teams will look at the world in a fresh way, notice new things and gather insights into the problem by active listening to relevant stakeholders instead of assuming what the problem is. In the Define/Synthesis phase, teams will try to make sense of all the possibilities identified in the Discover phase and then prioritize on the area to focus upon. In the Develop/Ideation phase, potential solutions and concepts are created by co-designing with a range of different people with different perspectives, prototyped, tested and iterated (trial and error phase). The Deliver/Implementation phase signals the phase where different solutions are tested at small-scale, rejecting those that will not work and improving the ones that will, to ready the concept for production and launch.

Co-Design - an approach to design that actively involves all stakeholders in the design and development process to ensure the resulting product or device is simultaneously useful, usable and desirable. Everyone who has the potential to impact the design as well as everyone who will be impacted by what is designed should ideally be involved in the co-design process. For medical devices, the people who have the potential to impact the design include all members of the project team together with other stakeholders who will be involved in designing, engineering, manufacturing, marketing, distributing, and selling the device. Those who will be impacted by the design include medical professionals, patients, caregivers, technologists, trainers, etc. Of course, it is not possible to engage all these potential co-designers, but the aim is to invite and involve a very diverse set of stakeholders in the Co-Design Studio. Three invention teams will be selected to

engage with three interdisciplinary teams of graduate students in a co-design approach to facilitate and catalyze the design and development of three medical device inventions. Students will select the invention they are most interested in working on.

Co-Design for Regulatory & Usability Requirements to assure that the device meets user needs and intended uses when operated in its intended environment; defines appropriate specifications; to build quality, safety, effectiveness and savings into your medical device; and can improve and prevent future issues. Almost half of voluntary recalls of medical devices may have been prevented with adequate design controls. Human Factors, important for design control, is the study of the interactions between humans and device (i.e., interface) and the subsequent design of the device-human interface. For medical devices, the most important goal of the human factors/usability process is to minimize use-related hazards and risks and then confirm that these efforts were successful and users can use the device safely and effectively. Specific beneficial outcomes of applying human factors/usability to medical devices (as applicable) include:

- Easier-to-use devices,
- Safer connections between device components and accessories (e.g., power cords, leads, tubing, cartridges),
- Easier-to-read controls and displays,
- Better user understanding of the device's status and operation,
- Better user understanding of a patient's current medical condition,
- More effective alarm signals,
- Easier device maintenance and repair,
- Reduced user reliance on user manuals,
- Reduced need for user training and retraining,
- Reduced risk of use error,
- Reduced risk of adverse events, and
- Reduced risk of product recalls.



Section II. Opportunity Information

Opportunity Mechanism	Customized Co-Design Studio for 3 Medical Devices supported by the CCTS Translational Innovation Program, Department of Design and other partners
Anticipated Number of Awards	Total number up to 3 is subject to a sufficient number of meritorious applications and number of graduate students enrolled in the class prior to January 11, 2021
Program Period	January 11, 2021 – April 19, 2021

How Can the Co-Design Approach Benefit your Innovative Medical Device?

- Set your medical device apart from the competition by generating qualitative valuation, such as pain relieved or lifestyle benefits your product provides. By thoroughly understanding and documenting this qualitative value through co-design approach, you can better explain the problems you are solving and the value proposition of your medical device.
- Enhance your entrepreneurial acumen through an experiential, project-based learning opportunity to explore stakeholder and clinical needs identification iteratively through 3 co-design workshops, ideation, prototyping, business model canvasing, FDA regulation, industry partnerships and other key components along an innovation's path to individual and public health impact
- Reduce the risk of failure
- Better device quality in terms of usefulness, usability, desirability and feasibility
- Harness and integrate the contributions of multiple stakeholder perspectives
- Obtain relevant feedback from the co-designers before it is too late to use their input; participation can build ownership in the product/device
- Proof-of-concept (POC) prototypes to mitigate risks or pivot to a different technology
- Strengthen leadership skills needed for experimentation, iteration and learning, allowing projects to be open and

agile, showing results along the way and being able to change.

- Improve meaningful engagement needed with patients and stakeholders, who are delivering the ideas and receiving them, but also with other partners who might have other ideas.
- Develop connections and build relationships which are as important as creating ideas for entrepreneurial success.
- Communicate visually and inclusively to help people gain a shared understanding of the problem and ideas.
- Iterate, iterate, iterate. Do this to spot errors early, avoid risk and build confidence in your ideas.
- Your device will be better able to contribute to just and equitable health futures

Section III. Eligibility Information

The Principal Investigator(s) (PI) must be Ohio State or Nationwide Children's Hospital faculty or staff with an appointment that allows them to serve as PI on an externally-sponsored research project. PI must possess a strong passion to see his/her invention commercialized. The PI is primarily responsible and dedicated to the best interests of the development of the medical device. Attendance at all 3 co-design workshops is required. There is no limit to the number of applications per PI. Residents, post-docs and staff are eligible to apply as co-PIs. Proposals must be a medical device developed to solve a health/clinical problem and improve the quality of human life that falls within the State of Ohio's technology focus areas of software/information technology and biomedical/life sciences. Projects are designed to advance the commercialization of university-owned (or NCH-owned) intellectual property. By the deadline, a technology must already have intellectual property protection (patent pending or patent issued), on file with the technology licensing team. This program is designed to prepare towards procurement of seed stage capital. Technologies with industry sponsorship, research grant support, investment partners or those that are the subject of a TVSF Phase 2 award are not eligible.

Device Definition- Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

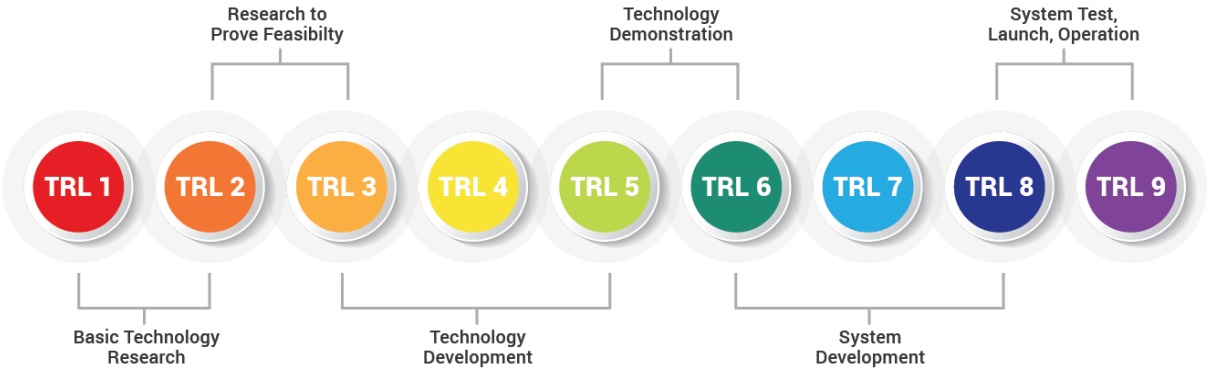
1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

Product Development Stage: This call will support stages 3 and 4 of the **Technology Readiness Level**.



This call is best suited for early intermediate stage for proving feasibility and acceptance in the marketplace especially when minimal R&D funding has been expensed but the project has already been assessed as a highly promising "idea" or

"concept" that is protected. The Co-Design Studio facilitates understanding the stakeholders and their context for validation of the problem, market, product, de-risking and internal market validation of new, emerging technologies as an important step in moving technologies from the lab for commercialization opportunities and garnering follow-on seed-stage capital investment. Co-design leads to creating better products or services from the perspective of users through rigorous, successive iterations to validate innovative ideas; cheaply and quickly test (sometimes risky and unproved) assumptions about customers, product, and market; talk to users and hack together prototypes through a different but well-structured validation process to minimize costs and to maximize your chance of a successful launch while meeting the stakeholder expectations.. A TRL 3-4 or earlier is ideal for human-centered assessment, Proof of Concept (POC), business model canvas and human factors/usability of university-owned technologies to the point that they are more competitive to attract seed funding. Seed funding such as the SBIR/STTR or Phase 1 (technology validation) of the Ohio Third Frontier Technology Validation and Start-up Fund (TVSF) is needed for more in-depth and costly technology validation. After procuring technology validation funds to complete Phase 1 work, these would either be ready to be licensed by an Ohio-based startup company upon completion or determined to be unfeasible for commercialization.

Section IV. Application Submission Guidelines

Submission Process. Applications will be submitted through an online REDCap form, which can be found on the CCTS Co-Design Studio webpage dedicated to this RFA s. ***Chrome is the preferred browser for this REDCap submission form***. Submit Full Applications by the deadline date and time listed in Key Dates*. Additional resources can be found on the CCTS webpage dedicated to this RFA. IMPORTANT: Please note that you are required to include a Lay Summary as part of the full application. You could also choose to prepare a 5 minute video which explains your proposed project to a general (lay) audience. Lay Summary (written or visual) must minimize jargon and promote readability and understanding at a nonscientific lay level. This will be used for recruiting patients and community members to the co-design studio.

Mandatory Meeting with Institutional Representative(s)

Before submitting applications, PIs are required to discuss the stage of the technology and commercial readiness of their project with the designated technology transfer representative at their institution (NCH or OSU). Your university tech transfer representative can assist in determining if the proposed project is appropriate for the Co-Design Studio. If you are unsure about whom to contact, please reach out to Dr. Tanya Mathew at Tanya.Mathew@osumc.edu.

Availability to Co-design with Graduate Student Teams

Applicants must commit to the requirements and timeline of the graduate student course as part of the application process. An interdisciplinary team of graduate students will be dedicating time over the semester to assess the extent to which the selected device is validated, useful, usable, feasible and desirable. The invention team will have access to the classes and hands-on coaching customized around each medical device for graduate students in the course. A combination of didactic and hands-on learning will be offered by experienced faculty, staff and entrepreneurs. Mentors with successful track records inventing and commercializing important health technologies will coach students which will benefit the invention team, too. PIs will have access to a group of experts (customized to your medical device) from industry and academia with expertise in Medical Device discovery, development, clinical investigation, health care delivery systems experts, regulatory experts, IPR and legal experts. Therefore, participation by at least one member of the invention team at each weekly class is strongly recommended to maximize the value of the graduate course. Most importantly, co-designing with stakeholders customized to your medical device is the main benefit of this studio for medical device inventors.

Preliminary Co-Design Studio 2021 Timeline

DATE	**ACTIVITY**	**HOMEWORK** (provided later)
January 11	• Introductions & Orientation • Overview of the course • Guest lectures on medical device commercialization (TBD)	
January 18	• **No school. Martin Luther King Day**	• Start required readings • Watch online recording: *FDA-regulated Research: Myth vs. Reality - Medical Devices. Part 1: Regulatory overview*

January 25	• **Pitch presentations by the inventor teams:** 45 minute overview followed by questions. • Student teams form around the inventions • Guest lecture (TBD) • Student teams meet to prepare questions for the February 2 event.	• Required readings
February 1	• Guest lecture (TBD) • Guest lecture (TBD) • Guest lecture (TBD) • Student teams meet.	• Required readings • One (or more) team members attends (via Zoom): *FDA-regulated Research: Myth vs. Reality - Part 2: Medical Devices* on *February 2 9:00 to 10:30*
February 8	• Student teams meet to prepare for Workshop 1.	
February 15	• **Workshop 1:** Inventor/student teams participate in collaborative visioning session. They also identify stakeholders to recruit and generate the plan for Workshop 2.	
February 22	• Student teams meet to discuss workshop results.	
March 1	• Student teams meet to finalize planning for the next workshop.	
March 8	• **Workshop 2:** Three co-design workshops (facilitated by the inventor/student teams) with key stakeholders to identify challenges to address and opportunities to explore with regard to the inventions.	
March 15	• Student teams meet to discuss workshop results.	
March 22	• Student teams meet to plan next steps.	
March 29	• **Workshop 3:** Three co-design workshops (facilitated by the inventor/student teams) with key stakeholders to explore solutions and future opportunities.	
April 5	• Student teams meet to discuss workshop results and analyze findings to date.	
April 12	• Student teams prepare final presentation and review with the inventor team for feedback.	
April 19	• **Final presentation** • Final project documentation due.	

Section V. Application Review Process & Criteria

Proposal Review Process

Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review. Self-contained proposals with essential supporting materials provided as uploads are recommended. The Co-Design Studio Selection Committee will make final recommendations after review and scoring of the submissions. The mission of the Translational Innovation Program of the OSU CCTS is to transform and advance the discipline of clinical and translational science at The Ohio State University and Nationwide Children's Hospital by translating innovation with technology transfer and commercialization. A key component of this mission is to convene and support new invention teams, which include the authentic inclusion of patients and community stakeholders at every level of the translational process.

Proposal Review Criteria

- Major criteria for evaluation by the review committee will be the inventiveness, quality and health impact of the Early Stage Medical Device
- Suitability for Co-Design methodology
- Clearly identified need for Co-Design Studio with stakeholders towards the ongoing design development of the device
- If possible, offer a variety of medical devices to ensure a rich learning experience for students.
- Aligned with the objective of the RFA and mission of CCTS and sponsor, NIH NCATS

- Strong and committed PI
- Degree to which the intellectual property is protected
- Level of technology validation with preference given to teams that are in need for additional proof-of-concept and feasibility up to TRL-3 or 4.
- Extent to which the technology fits with Ohio's industry base and supply chains and the team plans to remain in Ohio
- Commercial viability, size of market and reasonable path to market
- Likelihood that the proposed project will lead to a startup company
- Potential for subsequent extramural seed funding
- Potential for success and aligns with goals of the CCTS Translational Innovation Program
- Availability of key members from the invention team to meet (on Zoom or in 105 Hayes Hall) with the graduate student teams during class time on Mondays during Spring Semester. The five mandatory dates are shown in red on the timeline table. The class meets from 2:00 to 6:00 but the invention teams will only need to be available for about two hours on each meeting date.
- Availability of the PI or members of the invention team to answer questions from their student teams via email as needed
- CCTS commitment to inclusive entrepreneurship, fair prospects at the American Dream for all and to close the opportunity gap particularly for women and people of color.

Section VI. Studio Award Administration Information

Anticipated Announcement

CCTS program staff will send an email notification to the applicants of meritorious applications after the review process is completed on January 15, 2021.

Reporting Requirements

The PI must complete a final project report through REDCap following the completion of the course. PIs of invention teams are also required to complete annual surveys for five (5) years following the completion of the program. This is a requirement for reporting to the NIH about the outcomes of this program such as licenses executed, new start-ups formed, state or federal funding received, private capital raised and product introductions or sales. Links to these progress reports will be sent by e-mail.

Co-Design Studio Expectations: Successful completion of the Medical Device Co-Design Studio is expected to contribute to one or more of the following outcomes: license the subject technology; start a new business; complete a business plan suitable for review by third-party investors; submit Accelerator Award or TVSF/SBIR/STTR grant proposals; present in the Ohio Collegiate Venture Showcase, apply design methodology in respective fields; and prepare faculty and students to be entrepreneurially competitive and continue to engage in entrepreneurial activities.

Section VII. Program Contact

Please visit the **program webpage** for links to the REDCap application form and useful resources. If you have any additional questions, please contact:

TANYA MATHEW, BDS, MS
Research Specialist, CCTS Innovation, Commercialization & Entrepreneurship Program
Center for Clinical and Translational Science
Adjunct Assistant Professor, Pediatric Dentistry, College of Dentistry
Strategic Advisor & Chair, Health Disparities, Diversity Council, Wexner Medical Center & Health Science Colleges
383 Arps Hall ✆ 614-366-5856 & Remote 614-915-7486 @ Tanya.Mathew@osumc.edu
Pronouns: she/her/hers Honorific: Dr.