MUSC Entrepreneurship Certificate Syllabus

I. Course Overview:

At the beginning of the program you will come up with a novel technology that you wish to use as the foundation for your virtual "company". As you progress through the course content, you will complete exercises based on the content to assess the translational potential of your technology.

For Example: After completing the Understanding Intellectual Property and US Patents Deep Dive modules, you will perform a patentability search on your technology.

The program will close with learning economic practicality, how to pitch your idea, and how and where you can raise money. This overview will be layered in such a way that a budget plan can be generated and a business proposal written.

The course will be structured into six main modules – four of which will require full completion, and two of which that will require completion a minimum number of desired topics depending on which track you choose. The track should be chosen based on the technology you are working on in this course. There will also be a Policies and Resources module which will provide information related to MUSC and the region. Below you will find an overview of each of the all modules and a description of the online lessons within each module.

II. Identifying a Technology:

The technology you identify can be one you are currently researching or an idea you have that you think has potential. You will need to write up a non-confidential summary of the technology and turn it in for approval prior to starting the course. If you need help coming with a project, message the course administrator who can help provide ideas or brainstorm with you on what would be a project that fits well with the course.

Examples of projects:

1. A novel biologic that possesses anti-inflammatory qualities.
2. A known small molecule that failed for efficacy in fibrosis, but you believe could be repurposed as an anti-cancer agent
3. An imaging diagnostic for early detection of Alzheimer's Disease
4. A medical device knee implant that retains mechanical stability over time compared to current devices
5. A new antimicrobial material that would have use in implantable medical devices
6. A software that can help a provider diagnose and treat injuries remotely

Properties of Technologies that would be the best fit:

You do not need to have a complete product profile for the technology in terms of what it would look like on the market. That being said, you should have an idea that is formed enough to perform a prior art search and/or assessment of the technology compared to competitors. In the case of therapeutics, that would mean knowing the sequence, formula

or use of known compound. For a diagnostic, that would mean knowing the target or method needed to diagnose a disease. For a medical device, it would be at minimum a drawing (preferably a CAD drawing) or prototype of the device. For a software, it would be having either a workable product or design features that can be implemented that will distinguish the technology from other technologies.

**You should be in contact with your Technology Transfer Office (At MUSC frd@musc.edu) if the technology you are working on is associated with your University.*

III. **Online Modules:**

Lesson	Description/Activity	Length
Getting Started	*Required*	
Understanding What You Have	Science vs Invention vs Business. Understanding Key Issues in Innovation and New Product/Service Development.	0.5 hrs.
Business Opportunity	Defining and evaluating opportunity.	1 hrs.
Entrepreneurial Overview	How to determine if starting a company is the right move for you.	1 hrs.
Class Project	*Identify an idea for assessment of translational potential throughout the course.*	
Tangent: Intellectual Property	*Copyright or Patent Track required*	
Understanding Intellectual Property.	Review of the types of IP and protections afforded by each. *(All Tracks)*	0.5-1 hrs.
US Patents Deep Dive	Process, requirements, timeline and associated costs. *(Patent Track)*	1 hrs.
Case Laws that have Changed the Face of Patents	Myriad, Prometheus & Alice. *(Patent Track)*	1 hrs.
Foreign Patenting Strategies	How to determine in what countries to file patent applications. *(Patent Track)*	0.5-1 hrs.
Freedom to Operate	Differences between being patentable and not infringing. *(All Tracks)*	0.5 hrs.
Copyright	What is protectable, how to secure, and advantages provided	1 hrs.

Deep Dive	*(Copyright Track)*	
Open Innovation	open source software licenses (BSD, etc). *(Copyright Track)*	1 hrs.
Trademarks & Service Marks Deep Dive	What is protectable, how to secure, and advantages provided. *(All Tracks)*	1 hrs.
Balancing Act of Innovating in Academia	Balancing publications, presentations, and grants, while protecting IP. Strategies and trade-offs. *(All Tracks)*	0.5 hrs.
Class Project	*Perform a prior art search and preliminary assessment of freedom-to-operate on your idea. (Patent Track).* *Identify similar products either out in the market or being developed that could compete with your idea (Copyright Track)*	
Building Your Company	*Required*	
Developing a Business	Overview of Developing a Successful Business	2 hrs.
Company Creation	Different types of corporate structures.	1 hrs.
Building a Team	Identify your company's management team.	0.5 hrs.
Constructing a Business Plan	Product to Business Concept to Business Model to Business Plan.	0.5 hrs.
Economics of a Start-Up	Expectations about size, growth, returns, and risk.	1 hrs.
TBD	*Task TBD*	
Tangent: Regulatory and Reimbursement	*Device, Diagnostic or Therapeutic Track*	

Regulatory Overview	Role of FDA; paths and timelines; Regulatory bodies outside of the US (CE Mark). *(All Tracks)*	1 hrs.
FDA Medical Devices Regulation Deep Dive	Deep dive into device paths and review processes. *(Device Track)*	1 hrs.
FDA Regulation of Therapeutics Deep Dive	Deep dive into FDA review and clinical trials. *(Therapeutic Track)*	1 hrs.
FDA Regulation of Diagnostics Deep Dive	Deep dive into diagnostic development and review processes. *(Diagnostic Track)*	1 hrs.
FDA regulation of Digital Health Innovation Deep Dive	Deep dive into FDA regulation of digital health innovation development and review process. *(Device and Diagnostic Tracks)*	1 hrs.
Developing Products for Rare Diseases and Special Conditions.	Orphan Diseases; Humanitarian Use Exemption (HUD). *(Therapeutic Track)*	1 hrs.
Waxman-Hatch Provisions	Effects on drug approval, changes in formulations & dosing. *(Therapeutic Track)*	1 hrs.
Reimbursement	Commercial challenges, obtainment of a reimbursement code. *(Device and Diagnostic Tracks)*	1 hrs.
Regulatory Pathway task	*Determine how your technology will be regulated, and what studies will need to be done on the preclinical and clinical side, as well as a timeline of how long it will take for you to get to market*	
Tangent:	*Required*	

Agreements		
Confidentiality Agreements	Purpose; one-way versus two way; terms and implications.	0.25 hrs.
Material Transfer Agreements	Purpose when sending and receiving materials, terms and implications.	0.25 hrs.
Options and Licenses	Differences, structure, terms, definitions and purpose.	1 hrs.
Consulting Agreements	Management and provisions to watch for.	0.25 hrs.
Financing	*Required*	
Primer on Finance	Sources of funding; how and when to go for which source.	1 hrs.
SBIR/STTR Funding	Purpose, rule, requirements, agencies, etc.	1 hrs.
Art of the Pitch	Attracting investors.	0.5 hrs.
Crowd Funding	Sources and implications.	0.5 hrs.
Dilutive Funding	Sources and implications.	1 hrs.
Valuation and Deal Structure	How much is the product or company worth. Maximizing returns.	1 hrs.
Pitch your idea	*Develop a pitch deck for your technology and business*	
Policies and Resources	*IP Policy & Disclosures, Conflict of Interest, Startup Policy Required*	
IP Policy & Disclosures	Overview of IP policy, record of inventions, etc.	0.25 hrs.

Conflict of Interest	Overview of conflict of interest (COI) policy and the COI review process.	0.5 hrs.
Startup Policy	Overview of the MUSC startup Policy	0.5 hrs
IT and Networks	How IT support, MUSC networks and storage may be used for commercial purposes.	0.5 hrs.
Branding and MUSC Logo Use	Guidelines for when and how MUSC's logo may be used.	0.5 hrs.
Apps	Overview of app support at MUSC and relation to copyright policy.	0.5 hrs.
Local Resources	Regional services, facilities and companies geared towards fostering innovation.	0.5 hrs.
Fee for Service Policies	How cores and services can be used under a fee for service structure.	0.33 hrs.