

# *The MUSC Foundation for Research Development (“FRD”) and Technology Commercialization at MUSC.*



Scott Davis, PhD and Troy Huth, JD, PhD  
MUSC Foundation for Research Development



# What is technology transfer?



# Tech Transfer at MUSC

The MUSC Foundation for Research Development Primary Mission: To facilitate the translation of *all* MUSC discoveries into products and services for the public's benefit



Bench



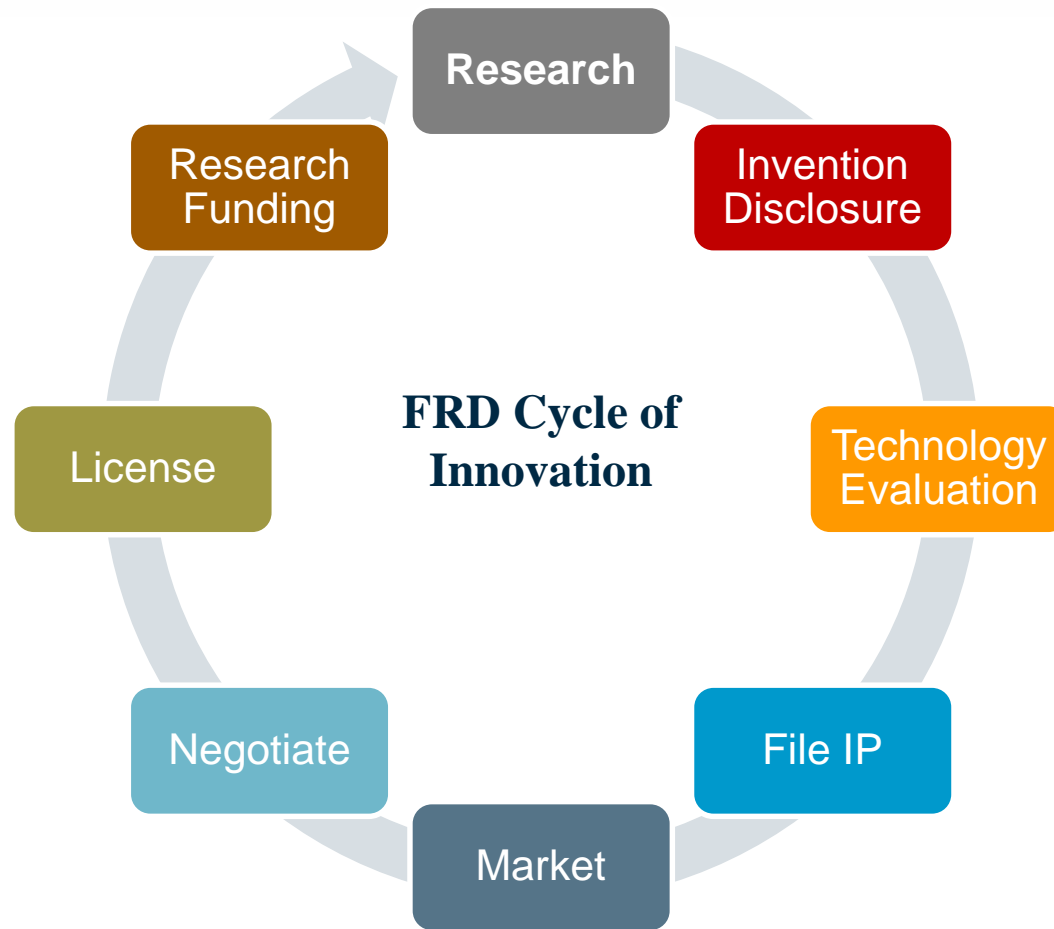
Industry



Bedside



# Tech Transfer Cycle of Innovation



# MUSC Intellectual Property (IP) Policy

**Who?** As a condition of your employment, studentship, and/or resource usage at MUSC you must assign ownership to MUSC

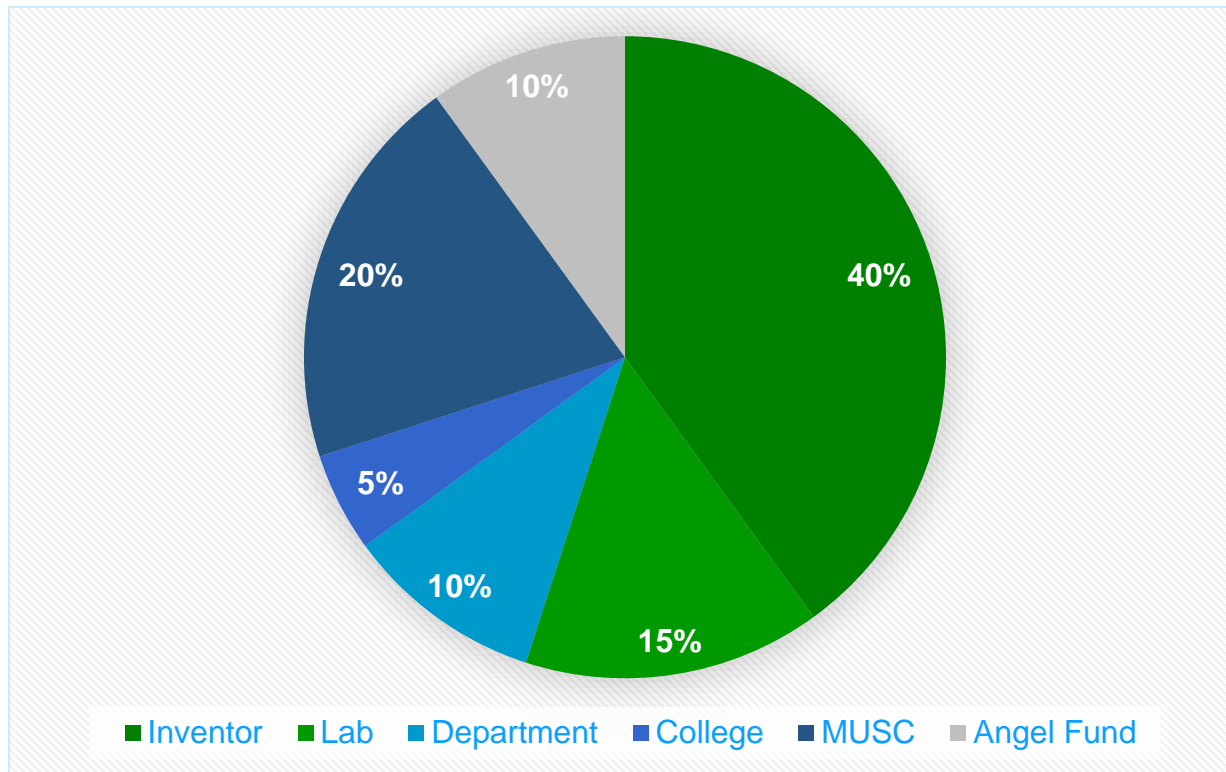
IP is required to be disclosed by employees and students

- › Ownership is then determined
- › Traditional academic copyrights owned by author(s)
- › Employee - MUSC entitled to ownership if in field or MUSC resources utilized
- › Student - MUSC entitled to ownership if IP invented during course of research at MUSC, utilizing MUSC resources, made in conjunction with others that must assign rights and/or preexisting commitments



# Licensing revenue distribution

First \$10,000 of Net Proceeds to inventor(s), then:



Net Proceeds = Gross Proceeds – [Costs + 15% management fee]

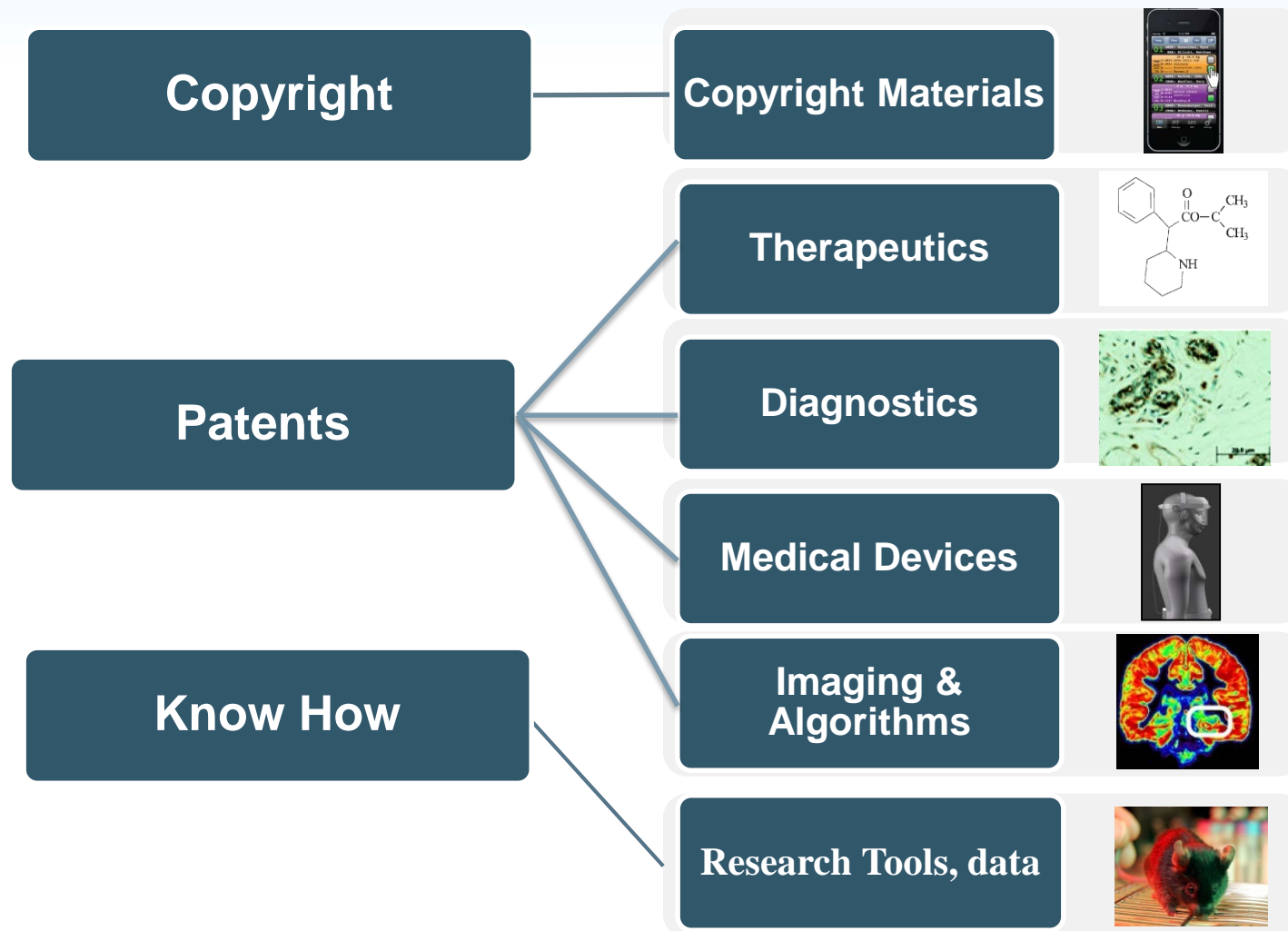
\*For Disclosures submitted on or after April 7, 2016



# What is intellectual property?



# How MUSC IP is Protected





# Research Tools

Research Tool - Proprietary or difficult to produce material to be utilized by others in research (non-commercial) activities.



MONOCLONAL ANTIBODIES



POLYCLONAL ANTIBODIES



CELL LINES



MOUSE MODELS



SMALL MOLECULES (TOOL COMPOUNDS)



VECTORS



PEPTIDES AND PROTEINS



ZEBRAFISH



RECOMBINANT ANTIBODIES



COLLABORATIVE TOOLKIT



LABWARE



BACTERIA



# Research Tools from MUSC

## Periostin, C-terminal Antibody

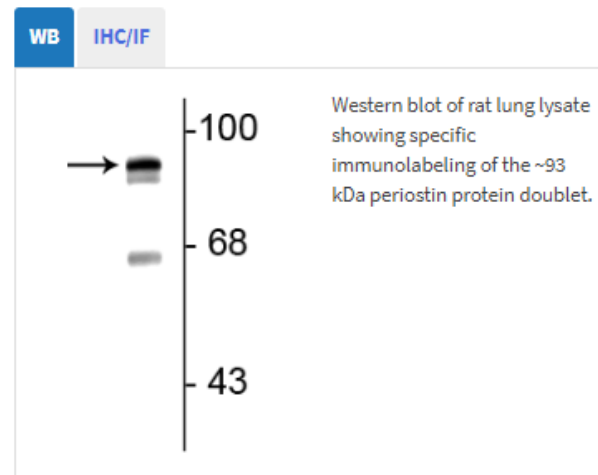
Catalog #: 1621-PERI

Categories: [Cardiovascular](#), [Extracellular Matrix Proteins](#)

Datasheet: 

Description	Storage	References
<b>Rabbit polyclonal antibody</b>		
<b>Formulation:</b>	Affinity purified	
<b>Species Reactivity:</b>	Rat, Mouse, Human, Chicken	
<b>Applications:</b>	<a href="#">WB</a> 1:1000 <a href="#">IHC</a> 1:100	
<b>Species:</b>	Rabbit	
<b>Gene Name:</b>	POSTN	
<b>Molecular Reference:</b>	~93 kDa	
<b>Cite This Antibody:</b>	PhosphoSolutions Cat# 1621-PERI, RRID:AB_2492205	
<b>Antigen/Purification:</b>	<a href="#">Expand</a>	
<b>Biological Significance:</b>	<a href="#">Expand</a>	
<b>Synonyms:</b>	<a href="#">Expand</a>	

Size	Price		
<input checked="" type="radio"/> 100 µl	\$365	<input type="text" value="1"/>	<a href="#">Add to cart</a>
<input type="radio"/> 25 µl	\$109		



- Developed by Dr. Stan Hoffman at MUSC
- Periostin C-terminal antibody



# Copyright ©

**Works of “Original Expression”:** May apply to a wide range of creative, intellectual, or artistic forms, or “works” that have been tangibly expressed

- › literary works (all text including computer software)
- › musical works
- › dramatic works
- › pantomimes & choreographic works
- › pictorial, graphic, & sculptural works
- › motion pictures & other audiovisual works
- › sound recordings
- › architectural work

**Scope of Protection:** The legal right granted to an author to exclusively use the expression of an idea

**Registration:** Copyrights are registered with the U.S. Copyright Office

- Division of the Library of Congress (Optional)



# Modified Barium Swallow Impairment Profile

Preview of the MBSImP Standardize...

## What Is The MBSImP Approach?

The Modified Barium Swallow Impairment Profile provides a standardized protocol to interpret and communicate swallowing impairment in a manner that is specific, consistent, accurate and objective.

[ENROLL NOW](#)

What is MBSImP | **Research** | Training & ASHA CEUs | By the Numbers | Beyond the Training | Questions

Research

Is the MBSImP Approach Evidence-Based?

- The Modified Barium Swallow Impairment Profile, or MBSImP, is a standardized approach to instruction, assessment, and reporting of physiologic swallowing impairment
  - A barium swallow is a test that may be used to determine the cause of painful swallowing, difficulty with swallowing, abdominal pain, bloodstained vomit, or unexplained weight loss
  - Can detect narrowing or irritation of the esophagus, swallowing disorders, ulcers, tumors/polyps and GERD
- Developed by Dr. Bonnie Martin-Harris at MUSC



# Patents

**Provisional Patent** - temporary priority document for utility patents

**Utility Patent** - process, machine, manufacture, or composition of matter

**Design Patent** - ornamental design on a useful item

**Plant Patent** - new kinds of plants produced by cuttings or other nonsexual means



# Utility Patents

## Requirements of Patentability

### •101: Utility

- useful/patentable subject matter

### •102: Novelty

- new, not previously known in the prior art

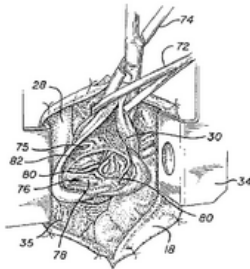
### •103: Non-obviousness

- elements not contained in the prior art with a motivation to combine

### •112: Enablement/Written Description

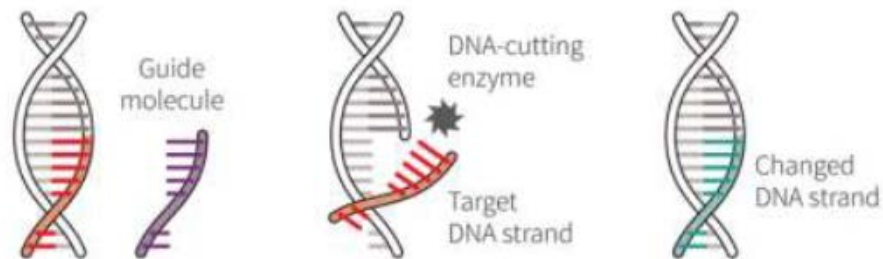
- the inventor is in possession of the invention at filing and the invention is fully described as to be reproducible by one skilled in the art.

<p>(12) <b>United States Patent</b> Cosgrove</p>	<p>(10) Patent No.: <b>US 6,182,664 B1</b> (45) Date of Patent: <b>*Feb. 6, 2001</b></p>
<p>(54) <b>MINIMALLY INVASIVE CARDIAC VALVE SURGERY PROCEDURE</b></p>	
<p>(75) Inventor: <b>Delos M. Cosgrove</b>, Hunting Valley, OH (US)</p>	
<p>(73) Assignee: <b>Edwards Lifesciences Corporation</b>, Irvine, CA (US)</p>	
<p>(* ) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).</p> <p>Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.</p>	
<p>(21) Appl. No.: <b>08/801,494</b></p> <p>(22) Filed: <b>Feb. 18, 1997</b></p>	
<p><b>Related U.S. Application Data</b></p> <p>(63) Continuation-in-part of application No. 08,603,313, filed on Feb. 19, 1996, now Pat. No. 5,752,526.</p> <p>(51) Int. Cl.<sup>7</sup> ..... <b>A61B 19/00</b></p> <p>(52) U.S. Cl. .... <b>128/898; 623/902; 623/914; 623/918; 623/922</b></p> <p>(58) <b>Field of Search</b> ..... <b>607/122, 126; 128/898; 604/19, 28, 49; 623/1, 2, 3, 1, 26, 2, 1, 3, 1, 902, 904, 915, 921, 922, FOR 101</b></p> <p>(56) <b>References Cited</b></p> <p>U.S. PATENT DOCUMENTS</p> <p>Re. 35,352 10/1996 Peters .....</p> <p>4,351,345 * 9/1982 Carney ..... 607/122</p> <p>(List continued on next page.)</p> <p>FOREIGN PATENT DOCUMENTS</p> <p>WO 93/01768 2/1993 (WO) .....</p>	
<p>OTHER PUBLICATIONS</p> <p>J. Card Surg., 1995, 10:529-536, M. Clive Robinson, MD et al.; "Minimally Invasive Coronary Artery Bypass Grafting: A New Method Using an Anterior Mediastinotomy".</p> <p>(List continued on next page.)</p> <p>Primary Examiner—V. Millin Assistant Examiner—Kelley O'Hara (74) Attorney, Agent, or Firm—James W. Inskeep; Guy L. Cumberbatch; Debra D. Coadino</p>	
<p>(57) <b>ABSTRACT</b></p> <p>A minimally invasive approach for surgery on portions of the heart and great vessels located between a point approximately three centimeters above supra annular ridge and the mid ventricular cavity. A parasternal incision is made extending across a predetermined number of costal cartilage, e.g., a right parasternal incision extending from the lower edge of the second costal cartilage to the superior edge of the fifth costal cartilage. One or more costal cartilages, e.g., the third and fourth, are then excised to provide access to the portion of the heart or great vessels of interest, and a desired procedure completed. The minimally invasive approach enables repair or replacement of the mitral or aortic valve.</p>	
<p><b>24 Claims, 17 Drawing Sheets</b></p>	



# Examples of Patentable Subject Matter

- Chemical composition
- Non-naturally DNA, RNA, peptide molecule
- Method of treating a disease/disorder
- Drug delivery composition
- Medical device for diagnosing or treating a disease/disorder
- Novel method of isolating/extracting a biological substance (may have value as a diagnostic)



# Blink Reflexometer



- Delivers eye puffs and uses high-speed videography to record blink reflex
- Objective data to detect concussions
- MUSC PI lead Dr. Nancey Tsai, and a ZIAN project
- Licensed to BlinkTBI, initially partnered with the Citadel





# When Do I Have Something for a FRD Disclosure?

(and when should I disclose it?)



# Consider all types of innovations

Have you:

- Identified a need?
- Gathered preliminary data to demonstrate POC?
- Conducted a quick internet search to see if the idea is unique?
- Do you plan or hope to continue development of the idea?



# Disclose to FRD BEFORE any Public Disclosures

- Manuscripts, public presentations (internal or external), dissertations, posters in public places
- Grant abstracts for awarded federal grants are public disclosures
  - › Awarded grants *may* be as well
- Public uses and sales
- USA allows a 12 month grace period against disclosure of your own work, there is no such grace period for any other country



# 102/103 – Public Disclosures as Prior Art

- U.S. Patents and patent applications
- Foreign Patents and patent applications
- Journal and magazine articles
- Books, manuals, and catalogs
- Websites and databases
- Conference proceedings
- Scientific papers
- Product literature
- Other public documents



# How is technology advanced at MUSC?



# Criteria to Pursue

## Factors Considered

- Technical Merit
- Protectability
- Commercial Potential

## Our Decision to Pursue:

**Does** reflect the likelihood that the technology will be able to be commercialized

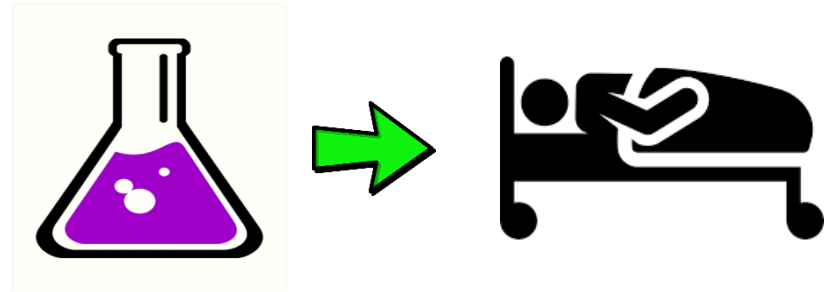
**Does not** reflect a judgment of the quality of the science nor the scientific importance of the discovery.



# Mechanisms to Advance

Typically University technology is at the pre-commercialization stage, how do we advance?

1. Internal development funds through SCRA, SCTR and FRD
2. Direct out licensing to development partner
3. Faculty Startup
4. Collaboration
  - Industry sponsored research
  - ZIAN
  - Clemson



# Internal Development Funds

- SCTR
  - Technology Development Fund
  - High Innovation High Reward
  - Discovery Grants
  - Telehealth Pilots
- SCRA
  - Prototyping Funds (Device)
  - Maturation Funds
- FRD
  - Prototyping Funds

## Internal Funding Opportunities

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### Predocctoral Students

- [SCTR TL1 \(T32\) Predocctoral Clinical & Translational Research Training Program](#)

### Postdoctoral Fellows/Junior Faculty

- [SCTR K12 \(K12\) Multidisciplinary Scholars Program in Clinical & Translational Science](#)
- [College of Medicine Clinician Scientist K12 Scholars Program](#)
- [Pilot Grants Program](#)
- [Program to Enhance the Retention of Clinicians \(PERK\)](#)

### Faculty

- [Pilot Grants Program](#)
- [Vouchers](#)
- [SCTR and MUSC FRD Technology Development Grants](#)

### Community Partners

- [Community-Engaged Scholars Program](#)





# Direct Out-Licensing

1. Prepare marketing materials for the technology.
  - Non-confidential Summary
  - Company List
2. Direct marketing to industry partners that are likely to have interest in the technology.
  - Market research
  - FRD contacts
  - Inventor contacts
3. Identify partner and negotiate agreement
  - Option/technology development license
  - Exclusive license agreement
4. Further development conducted by industry partner
  - License specifies development plan
  - Milestone ensure progress
  - May or may not include input/involvement from the inventor.



# Faculty Startup

1. Faculty expresses interest in forming a university startup
  - Initial meeting with FRD
  - Develop plan to move forward
2. Outside resources available for support
  - Legal contacts
  - SBIR/STTR consultants
  - Regulatory consultants
3. Example of early life of a University startup
  - Faculty identifies technology and creates company
  - Proof of concept: Phase I SBIR/STTR under technology option
  - Pre-clinical development: Phase II SBIR/STTR with technology license
  - Clinical development:
    - Through startup: Investors/industry partners
    - Independent of startup: Sublicensing/acquisition



# Collaboration

Technology needs further development before commercialization is possible? → Collaboration!

## Collaboration Partners

- Near limitless potential partners
- Common partners:
  - Therapeutics
    - Industry partners: SRA
    - CRO's: \$\$\$
    - UNC Eshelman SoP
  - Software/Apps
    - Internal MUSC resources
  - Devices
    - Clemson
      - Senior design
      - Designing with docs
    - ZIAN

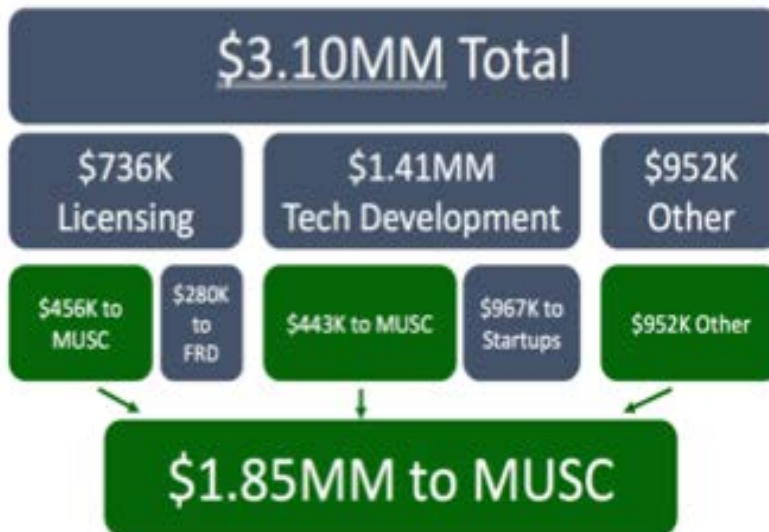


# What has FRD been up to?

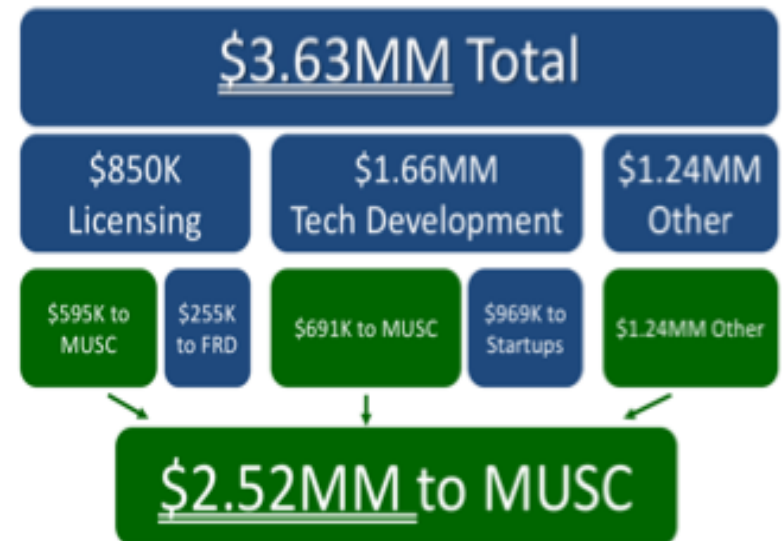


# FRD Value Added 2017 vs 2018

## FY17 FRD Value Added



## FY18 FRD Value Added



# Benefits of working with FRD

- FRD pays patent costs for technologies
- Protecting and Commercializing Technologies
  - › FRD experts in patenting and licensing with connections in industry
  - › Sponsored Research Funding, industry collaborations, commercializing technologies developed at MUSC
- Technology Maturation Programs
  - › SBIR/STTR program
  - › Directing to relevant funding (SCRA, SCTR, TAC)
  - › FRD prototyping fund
- Complying with IP policy



# How to Get Started?

## Record of Invention (ROI)


<http://academicdepartments.musc.edu/frd/inventors/inventors.forms>

Call FRD or email us at [frd@musc.edu](mailto:frd@musc.edu)

## Before a public disclosure!

Including:

- › Publication of the paper, poster in hallway, student presentation, departmental seminar, discussion with colleague from other institution, grants submitted

 MUSC Foundation for Research Development

**Confidential**  
MUSC Record of Invention (ROI) Form

**1. Detailed Information on Inventors:**  
[Please provide name, home address, country of citizenship, email address and Department for each Inventor. Space for additional inventors at the end.]

	Inventor #1	Inventor #2	Inventor #3
Name			
Position			
Department			
MUSC Campus Mailing Address			
MUSC Office Location			
E-mail Address			
Work Telephone			
Home Address			
Home Telephone			
Citizenship			
Point of Contact for all correspondence			

**2. Title of Invention:** [Title should be sufficiently descriptive to identify the Invention yet not reveal unique unpublished details.]  
■

**3. Do any of the inventors have an appointment with the VA (WOC, DAP or other)?**  
If so, who, what and when is appointment effective?  
■

**4. Was Federal Funding used to support the conception or actual practice of this invention?**  
If so, list Contract Name, Grant/Contract No. and PI  
■

**5. Brief Description of Invention** [Please summarize your invention describing the unique characteristics and advantages over existing technology.]  
■

Revised October 2012 1 FRD File No.: \_\_\_\_\_



# FRD Staff

## Contact info:

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- › 135 Cannon Street Suite 101L
- › Website - <http://frd.musc.edu>



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# Questions?

