Technology
COMMERCIALIZATION

MARKETING, OPTION AND LICENSE AGREEMENTS, AND STARTUPS
FRD is committed to finding the best possible industry partner to commercialize MUSC technologies. FRD endeavors to connect with marketing targets that specialize in the field of the technology and will commit significant resources to bring the technology to market.

FRD pursues multiple avenues to market MUSC technologies. These include listing the technology in numerous databases used by industry scouts, targeted marketing campaigns, trade shows, eCommerce, and social media outlets.

Technology Databases
With feedback from the inventors, FRD develops a one to two-page summary of the technology, called a Non-Confidential Summary (NCS). The NCS includes an overview of the technology, a brief market analysis, a listing of inventors, and hyperlinks to publications and published patent applications/patents.
FRD posts the NCS for all MUSC technologies via Technology Publisher, an online database through which users can search and view MUSC postings. Technology scouts and representatives from biomedical industry companies use these databases for new technology alerts and to search for relevant listings. These listings are centrally located on the Technology Publisher database and are accessible either via FRD’s website or via internet searches. The NCS is then posted to four additional databases – iBridge Network, Association of University Technology Managers Global Technology Portal, Flintbox, and Collective IP.

Databases with MUSC’s NCS listings:
- FRD (www.academicdepartments.musc.edu/frd/)
- iBridge Network (http://www.ibridgenetwork.org/)
- Association of University Technology Managers Global Technology Portal (http://gtp.autm.net/)
- Flintbox (http://flintbox.com/)
- Collective IP (https://www.collectiveip.com/)

Targeted Marketing
The FRD generates individualized marketing campaigns for technologies at varying points in the development process. Through surveying the marketplace, FRD identifies the key players and builds a contact list that encompasses a blend of large-cap companies, mid-cap companies, startups, and accelerators that will be interested in the technology being offered. FRD develops a non-confidential package to convey to the identified contacts. Depending on the stage of the technology, the non-confidential package may include any of the following: a non-confidential executive summary, publications, presentations, and published or issued patent applications. Additionally, FRD confers with the inventors to ensure that it has contacted all the companies with whom the inventor has a relationship.

Trade Shows
FRD attends several trade shows a year, which serve to connect directly with corporate decision makers of companies that in-license technology. FRD sends delegates to BIO International (sponsored by the Biotechnology Industry Organization), SC BIO, and Southeastern Medical Device Association conference. Trade shows provide FRD centralized access to executives from companies varying from start-ups to the largest pharmaceutical and medical device companies.
**eCommerce**
Additionally, FRD is pioneering the use of an eCommerce platform to market and license certain software and copyrighted materials. Interested parties view a technology listing in an online, global database, agree to a license agreement, pay securely, and instantly download materials. This avenue is often suitable for technologies such as curricula, software, or checklists and protocols that can be delivered online.

**Social Media**
FRD also promotes MUSC technologies through social media outlets. FRD utilizes LinkedIn to connect and communicate with potential commercial partners, researchers, and MUSC alumni. FRD tweets pertinent information to its Twitter followers at least twice a week. The FRD also distributes a monthly newsletter via email which highlights activity at the FRD and groundbreaking technologies. Currently, more than 350 people are subscribed to the FRD newsletter.

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**Option Agreements**

An option agreement provides a company short-term exclusive rights to negotiate a license to a technology. The option agreement prohibits FRD from licensing the technology to a third party during the term of the option agreement. Options are often used with faculty startups that may not yet have adequate funding to support the fee schedule of a full license agreement, but still need to acquire some rights in an FRD technology. The payments required for an option agreement are considerably lower than those for a license, and thus provide a much lower-cost method by which a faculty startup may acquire temporary rights in a technology. An option agreement is sufficient to support an SBIR or STTR grant application.

It is important to note, however, that options only provide the startup with a right to license, and a full license agreement will always be necessary before a company can obtain long-term exclusive rights in a technology. Additionally, option agreements limit the company’s use of the technology to research and development. Option agreements do not permit a company to generate revenue from the technology. A company must have a license in order to financially benefit from the technology.
License Agreements

License agreements are the mechanism that allows a company to have access to, use, and financially benefit from MUSC intellectual property. Licenses are intricate documents that are negotiated on a case-by-case basis, depending on the needs of the parties and how to best serve the technology. There are many provisions that are common to license agreements, including the license grant, sublicensing rights, diligence provisions to ensure continued development of the technology, royalties, minimum annual royalties, milestone payments, transaction fees, term/termination clauses, and indemnification.

Since license agreements are a very specialized type of contract, FRD always recommends that licensees hire an experienced licensing attorney to represent the company’s interests, especially for startup companies. While FRD wants to put startups on the path to success, the fact is that in license drafting, FRD represents MUSC’s interests. Thus, licensees should have counsel representing the company’s interests.

License Grant

The License Grant is typically the first major section of a license agreement, following the introductory language and the definitions. The Grant section details which rights associated with the given technology FRD is giving to the licensee. Specific provisions in the License Grant will determine whether the license is exclusive, whether the license is restricted to the use of the technology in certain fields of use or geographic regions, and whether the licensee may sublicense their rights to the technology (see paragraph D, “Sublicensing Rights”).

Also contained within this section are two important provisions. First, all FRD licenses will contain a Reservation of Rights, which allows MUSC and any entity thereunder to continue to use the technology for educational, research, and medical care purposes. This allows the MUSC inventors to continue their research on the technology without infringing on the license. Second, this section will contain an acknowledgment that any technology based on federally-funded research must comply with the provisions of the Bayh-Dole Act. The full text of that act can be found at http://www.law.cornell.edu/uscode/text/35/part-II/chapter-18. If you have specific questions about Bayh-Dole, please contact the FRD.
Sublicensing Rights
Sublicense agreements occur when a third party wishes to utilize the rights granted under a license. The sublicense is negotiated by the licensee (the original company which licensed the technology) and the sublicensee (the additional company which wants rights to the technology). FRD is not involved in the actual sublicense negotiations, but reserves the right to approve or deny sublicenses. Sublicense agreements are required to maintain certain terms and conditions of the original license agreement.

Diligence
The Diligence portion of a license agreement governs the efforts the Licensee must make in order to maintain its license to the MUSC technology. From a philosophical standpoint, this is the most important section of the license, because FRD wants to ensure that the licensee will work steadily towards bringing the technology to the marketplace, and thus to the bedside.

Often, this section will begin with a “general diligence provision”, requiring the licensee to diligently proceed with the development of the technology using earnest and commercially reasonable efforts. This is typically followed by a laundry list of “specific diligence provisions”, which vary greatly from license to license. These will set milestones in product development that must be completed by a specified date. The Diligence section will also contain a requirement for annual progress reports to be sent to FRD, to keep us apprised of the development of the technology, and to help enforce compliance with the specific diligence provisions.

Royalties, Milestones, and other Consideration
The Royalties and Consideration section of the license contains the various payments due to FRD throughout the lifespan of the license. These are all highly variable, and are negotiated from license to license. The fees may consist of one or more of the following types:
- A flat license fee due at signing, commonly called the “Upfront Fee”;
- A “Transaction Fee” due upon any sale, merger, or other liquidation event of the licensee company;
- Royalty payments, which are calculated as a percentage of sales of licensed products or methods;
- Maintenance fees and minimum annual royalties (MARs), which are payments made annually to continue to the rights granted under the license; MARs count towards royalties that accrue in the year following the payment of the MARs, but are not refunded if royalties do not accrue
- Sublicense fees, which are calculated as a percentage of any revenue attributable to the sublicensing of rights to a 3rd party; and/or
Milestone payments at various points (IND filing, various points in clinical development, FDA approval, first sale of product, patent issuance, etc.). The amounts and types of payments will depend largely upon the totality of the rights conveyed under each particular license. While it is not typically included in the Royalties and Consideration section of a license, one cost that is universally paid by the licensee is patent prosecution costs.

**Term and Termination**
The Term and Termination portion of a license agreement contains provisions that lay out the term, or lifespan, of the license, as well as the circumstances under which one or both parties may terminate the license. Typically FRD makes this section very licensee-friendly. Licensees may be allowed to terminate at any time with a set notice period, whereas FRD generally can only terminate under very specific circumstances. License lifespan is highly variable, and depends largely on the particular technology covered by the license. Often, if the technology is a patentable invention, the term of the license will be coextensive with the lifespan of the all covered patent claims.

**Indemnification**
Indemnification provides one party to an agreement protection from lawsuits resulting from the acts of the other party related to the agreement. The indemnifying party agrees to pay any and all losses, including legal fees for defense, arising from its conduct in relation to the agreement in place of the indemnified party. As a state entity, MUSC is legally unable to indemnify others. MUSC also requires that all potential licensees provide indemnification to the University in their licenses.

For example, Bouncyballs International licenses an innovative ball called the Bouncyball 3000 from MUSC. Bouncyballs International manufactures the Bouncyball 3000 and sells them to the general public. Bouncyballs International uses radioactive material in the production of the balls. If consumers were to sue Bouncyballs International and name MUSC in the lawsuit, Bouncyballs International is required to pay for MUSC’s costs associated with defending the suit and any judgment against MUSC.

Of course, these sections are only an overview of the terms contained within a license agreement, and there are numerous other specific provisions, which are also important for licensees to read and understand when licensing a technology.
What is a startup company?

A startup is a new company, formed by one or more entrepreneurs for the purpose of commercializing one or more pieces of intellectual property. Startups based on MUSC technologies can be formed by the inventors, outside parties interested in developing the technology, or a combination of the two. Startups serve an essential function for advancement of technologies that are too nascent to attract investment from larger, more established companies. Often, a startup will invest in several stages of technology development and then transfer the rights to a larger entity through sublicensing or acquisition of the startup.

Can a startup license technologies from FRD?

In short, yes. When appropriate for continued development of a technology, FRD licenses technologies to faculty members who have created startup companies. Importantly, however, startup companies will be evaluated by the same standards used to evaluate all potential licensees. Therefore, if a faculty member wishes to license his or her invention by creating a startup, FRD will require that the startup has a clear business plan, is able to raise capital or other development funds, and has a comprehensive product development plan. The Center for Innovation and Entrepreneurship helps faculty startups develop these business and product development plans.

Conflict of Interest Considerations

MUSC recognizes that the pursuit of innovation and technology development may lead to conflict of interest in relation to an inventor and/or entrepreneur’s MUSC activities and responsibilities. Conflict of interest does not imply wrongdoing; however, federal regulations require that academic Institutions identify potential COI and ensure that they are effectively managed.

The first step in COI compliance is timely disclosure of all outside activities. Employees are required to submit an annual disclosure (www.musc.edu/coi) during the annual disclosure cycle, April 1-30 each year. Throughout the year, the disclosure must be updated within 30 days if an existing relationship changes or a new relationship develops. Disclosures must include reporting of licensed technology, equity in faculty start-ups, income from faculty-start-ups, receipt of royalties related to licensed technology, and concurrent research related to these interests. It is important that employees notify the COI Office when planning to engage in MUSC research related to their intellectual property and/or equity interests so that potential COI can be reviewed and managed in compliance with federal COI regulations.
Consistent with AAMC best practices, human subjects research on technology developed at or by MUSC (i.e., technology in which MUSC has intellectual property rights) may not be conducted at MUSC. In the event there are compelling circumstances, any exception would first require Institutional approval and rigorous conflict of interest review and management measures before being permitted.

Guidelines for the involvement of students and trainees on projects in which a faculty member has a financial interest can be found at https://mainweb-v.musc.edu/grad/students/forms/conflict/.

Employees should read and understand the MUSC/MUHA COI Policy and the Industry Relations Policy to ensure their compliance with relevant university, state and federal guidelines.

If you have any questions or need guidance on COI issues, please contact the COI Office at 843-792-5907 or conflicts@musc.edu.