Senior Project Proposal

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I. Title:

Unblocking Innovation: Removing Barriers for Physician Sponsored Investigational Device Exemptions

II. Statement of Purpose:

Daily, physicians modify medical devices in off label, or unapproved, ways when faced with the decision of an invasive surgery or modifying medical, often endovascular, devices. But how can a company make it easier for physicians to comply with FDA expectations around Physician Sponsored Investigational Device Exemptions (PSIDEs)? Is there a way to remove roadblocks for physicians when hospitals have to complete FDA submissions? I am attempting to create a template and guidelines to decrease the workload around PSIDEs for physicians.

III. Background:

Engineering and medicine fascinate me. I became interested in medicine due to a series of injuries, specifically a torn ACL. I had to decide between surgeons, and I wanted to get back to athletics as quickly as possible. The local surgeon didn't collect data regarding his success rate, and he wouldn't release me to mountain bike until 9 months at the earliest. The surgeon that I went with collected his data and expected a return to sport in 6 months. I was back on the mountain bike after 2 months.

Listening to my surgeon compare different ACL surgeries and outcomes piqued my interest in medicine as a practice. There were many factors that created a more successful surgery. With other surgeries, many associated orthoscopic surgeries that left little or no scars as more successful. Many utilized different grafts with delayed results because they were seen as novel. Many people don't like the idea of having to do physical therapy on both knees with contralateral ACL reconstruction, or an ACL reconstruction where the graph is taken from the healthy knee, while differing physical therapy creates faster rehabilitation.

I have always loved finding solutions. From solving math problems to fixing my own problems, I have always been geared towards finding a solution. Engineering is about finding solutions. I love the problem solving it provides- you can create anything that comes to your mind and can alter the world in any way. It’s endless opportunities pair perfectly with medicine in biomedical engineering.

Approaching medicine from an engineering standpoint is a fascinating way to improve surgeries, solve medical issues, and advance medicine overall.

I am hoping this internship will allow me to help create a solution for companies to help physicians remove roadblocks regarding device modifications. Going into this internship without prior engineering experience, I hope to find out if I want to pursue biomedical engineering as a possible career path. I am excited to collect data and gain research experience.

IV. Prior Research:

The dangers of off label use range from minimal to drastic, but it can often be necessary for physicians to operate off-label when a certain medical device doesn’t

exist. For example, with abdominal aortic aneurysms, there are currently no devices that accommodate branching vessels with endovascular devices, so physicians are faced with the option of modifying company devices in off label ways or operating an invasive surgery. Off-label use is defined as the "unapproved use of an approved medication or product" (Hathaway & Cahill, 2023). Daily, physicians modify devices in off label ways when faced with the decision of an incredibly invasive surgery or modifying endovascular devices, but these actions can come with great risk. If unsatisfied with the result, the patient can sue the physician, device company, and the hospital because the actions taken were not backed by the Food and Drug Administration (FDA).

In order to align with FDA expectations and regulations when physicians are modifying devices, an Investigational Device Exemption (IDE) request needs to be approved by the FDA and Institutional Review Board (IRB). When submitting a Physician Sponsored Investigational Device Exemption (PSIDE), the physician takes on the role of the sponsor (the person pushing for the study and supplying the devices) along with the investigator (the individual operating or testing and collecting data of the modified device) which is a lot of work and time. Along with that, individuals or companies are prohibited from commercializing or promoting an IDE. There are many forms, acceptances, qualifications, and agreements to go forward with the study that must be approved before operating or testing the modified devices. There have been various cases with physicians modifying devices with PSIDEs that have been successfully tested. Several studies have been conducted with PSIDEs and endovascular grafts for aortic aneurisms and diseases. An "endovascular stent-graft

repair of aortic pathologies is a minimally invasive alternative to open surgery" with GORE TAG in order to decrease mortality rate brought on by an invasive surgery (Sze, 2023). Another case had similar positive results. Modified devices minimized blood loss, shortened the hospital stay, created quicker recovery, reduced general anesthesia requirements, and utilized a less invasive procedure (White, 2023). Similarly, another ongoing investigation for endovascular PSIDE grafts for juxtarenal aortic aneurysm treatments yields continual positive results. The physician describes physician modified endovascular graft (PMEG) devices as prohibited to be "manufactured or sold within the United States… but is easily available under our investigational device exemption (IDE) clinical trial" (Starnes, 2022). By modifying devices as a PSIDE under FDA regulations, involved parties avoid legal issues such as lawsuits and are able to modify devices for the betterment of society and medicine.

V. Significance:

Modifying devices in off label ways is often necessary but presents a risk to everyone involved. PSIDEs and device modifications allow physicians to utilize less invasive methods that lower mortality, decrease blood loss, shorten hospitalization, create quicker recoveries, and avoid invasive surgeries when possible. It is important that physicians are able to utilize these devices and modifications without serious roadblocks preventing PSIDEs when facing the decision of what to do without the option of provided devices. For example, in pediatric cardiology there is a serious lack of necessary medical devices, so "an approved device was utilized for an off-label application in 63% of patients and in 50% of all interventions performed" over a 3-year period (Sutherell et al, 2010). Through researching how companies can remove

roadblocks for physicians to create PSIDEs and comply with FDA laws and regulations, physicians will be able to modify devices to fit patient needs without creating heightened legal risk for the hospital, device companies, and physicians themselves.

I am interested in finding a way to remove roadblocks for physicians that will benefit the community. Through working on this research project, I am hoping to learn about biomedical engineering regarding medical devices along with the requirements necessary for device design regarding FDA laws. Bringing in a fresh perspective, I am determined to find an effective way to solve this issue. I am planning on sharing my findings with W.L. Gore (Gore). Many device companies, hospitals, and physicians can benefit from the findings from the final presentation. Having companies like Gore present an easier way for physicians to act within FDA regulations and create PSIDEs will allow the company to create greater legal security around its devices while benefiting every party involved.

VI. Methodology:

I will be working with W.L. Gore to research how to remove barriers around the creation of Physician Sponsored Investigational Device Exemptions (PSIDEs). I will be working with Roberta Bloss, my mentor and a W.L. Gore engineering leader. Through self-computer research, I will be learning the requirements of what is needed when creating an IDE or PSIDE and reviewing what companies can provide to make the PSIDE process progress faster and smoother, from product research to figuring out what is necessary for an Institutional Review Board (IRB). I will record what is

necessary and providable in the PSIDE process while meeting necessary FDA standards.

Plan for Research:

- Conducting remote computer self-research
    - Look at what stays consistent between IDE and PSIDE and can generally be provided for every IDE or PSIDE.
        - I will be looking at websites presented by the FDA and examples of approved IDEs from CSM.gov.
    - Look at what companies are able to provide for individual modified devices in order to create a PSIDE.

Plan for Deliverable Final Product:

- Create a template and guidelines.
    - Template goal: a pdf template that physicians will be able to fill out for PSIDE approval and include all required IDE information.
    - Guidelines goal: a pdf that provides a concise description of what companies are able to provide to physicians for PSIDE approval.

VII. Problems:

The main problems I expect to run into will surround available information on the internet. There is little record of how often devices are modified and used off-label, although it is common. There may also be an issue surrounding what articles I can access when conducting my research.

VIII. Budget: While there is no payable budget for this proposal, costs that will be incurred will include driving to and from my internship, my time, and the time of my mentor.

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