THE VALUES AND ETHICS OF BIOMEDICAL ENGINEERING PRACTICES IN THE DESIGN OF NOVEL BIOTECHNOLOGIES

BY

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DISSERTATION

Submitted in partial fulfillment of the requirements
for the degree of Doctor of Philosophy in Library and Information Sciences
in the Graduate College of the
University of Illinois at Urbana-Champaign, 2020

Urbana, Illinois

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ABSTRACT

Many novel biomedical technologies are currently in development at university-based laboratories across the United States. They are designed to provide cutting-edge diagnostics and treatments to patients within clinical settings. The primary designers of these novel technologies are biomedical engineers working in laboratory groups affiliated with academic biomedical engineering departments. In this project, the laboratory design practices of two types of biomedical engineering groups are examined. Cellular biomedical engineering laboratories develop novel cell-based technological systems used for genetic engineering, synthetic biomaterials, and nano-sized drug delivery systems. Biomedical device engineering laboratories develop novel device-based technological applications used in conjunction with MRI machines, ultrasound devices, and prosthetic apparatus. The findings of this study indicate biomedical engineering laboratory practices happen within the broader institutional context of translational medicine. The NIH conceptualizes translational biomedical research along a five-stage progressive roadmap of scientific activities, and in this project, depicts the starting research location of both cellular and biomedical device engineering laboratories. This initial location suggests how institutional actors from government, industry, and university, shape the design practices of each type of biomedical engineering group.

This study relies on literature from science and technologies studies, library and information science, and values and design, to ask questions concerned with three primary areas: the impact of values on the design of novel biomedical technologies, the suggested values implications of these design practices, and the proposed ethical design interventions for biomedical engineering laboratories. Using a triangulation methodological approach, data were gathered from 300+ hours of observations, 44 semi-structured interviews, and hundreds of pages of laboratory and academic department documents. The findings suggest that the laboratory

research and development activities of both cellular biomedical engineers and biomedical device engineers implicates the values of responsibility and transparency. The laboratory practices of cellular biomedical engineering laboratories adversely impact their self-perception as responsible actors in the design of technology, contribute to the conflated use of the term translation, and remove patients as the imagined end users. The laboratory activities of biomedical device engineering laboratories contribute to the perception that core devices altered with novel applications remain safe for continued clinical use, and to the devaluation of biology by turning complex physiological processes into abstract representations. Proposed ethics-based design interventions position biomedical engineering laboratories within a sociotechnical context and target both the laboratory level and institutional level.

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CHAPTER 1: INTRODUCTION

Many novel biomedical technologies are currently in development at university-based laboratories across the United States. These technologies are designed to provide cutting-edge diagnostics and are intended to treat patients within clinical settings. One important group of designers of these novel technologies are biomedical engineers who work in laboratory groups affiliated with academic biomedical engineering departments (Makin, de Vignemont & Faisal, 2017; WHO, 2017; Taktak, et al., 2019). Each group establishes its own research agenda and works to develop various types of novel biomedical technologies. Although the categories used to classify novel biomedical technologies are far from standardized within the field, laboratory developments typically fall into one of two distinctly different groups: cell-based technologies or device-based technologies. Novel cell-based biomedical technologies are designed to work at the micro- or nanoscale. They include genetic therapies, biomaterials, and drug delivery systems. Novel device-based biomedical technologies are those that propose to incorporate new applications (including hardware or software) with clinical devices. Some examples include altered MRI machines, ultrasound devices, and prosthetics. None of the novel biomedical technologies presented in this dissertation project are currently used within clinical settings.

Biomedical engineering laboratories engage design activities as they function within a broader institutional context. These activities are influenced by actors from the areas of university, industry, and government. The triple helix model suggests there are reciprocal linkages among university, industry, and government actors that drive technological innovation (Etzkowitz & Leydesdorff, 1995). The research projects of biomedical engineering laboratories are shaped by the real and perceived expectations of this triple helix, and these expectations affect how and which values impact laboratory practices. Biomedical engineering laboratories, for instance, are members of academic departments, which are located within disciplinary

colleges, which are then also located on university campuses. Each aspect of the university system plays a role in how biomedical engineering laboratories determine their technological design priorities. Many university-based biomedical engineering laboratories also have or want to have partnerships with different industry actors. For example, a biomedical device engineering laboratory may receive research funds from a private company, and a cellular biomedical engineering laboratory may seek to work with industry partners who can upscale the production of their novel technology. Biomedical engineering laboratories also have an important and profound relationship with government actors. Laboratories may seek out patents for their research developments, or they may try to anticipate which aspects of their novel technologies are more likely to receive approval from the U.S. Food and Drug Administration (FDA). One of the most influential governmental agencies to impact the laboratory design practices of biomedical engineers is that of the National Institutes of Health (NIH).

The NIH invests more than $37 billion annually in medical research, and more than 80% is disbursed to universities, medical schools, and other research institutions around the world (Philippidis, 2019; NIH, 2020a). The mission of the NIH is to gather knowledge about the behavior of living systems and determine how to apply that knowledge to enhance health, lengthen life, and reduce illness and disability (Henderson & Shanker, 2017). Since the early 2000s, the NIH has increased its ideological and financial support for research projects that align with the principles of translational medicine. The translational framework adopts a “bench-to-bedside” approach, which encourages biomedical researchers to focus on moving laboratory projects from the scientific workbench to the clinical bedside of patients. Biomedical engineering communities have come accustomed, both implicitly and explicitly, to the use of translational principles to describe their laboratory activities. This dissertation project seeks to contextualize and critically examine the laboratory activities of both cellular biomedical engineers and

biomedical device engineers within this translational context. The NIH's multi-stage translational roadmap will be used to conceptually ground this analysis.

1.1 Problem Statement

The use of novel biomedical technologies may result in negative social impacts (e.g., unequal access to care, unintended consequences, privacy violations) if the potential of these impacts is not considered throughout the technological design process. In a recent Technology, Entertainment, Design (TED) talk by American biochemist Jennifer Doudna, one of the designers of the CRISPR-Cas9 gene-editing technology, she made the argument for asking ethical questions about the potential clinical use of this novel cell-based technology. Although current use of this technology is almost entirely confined to the laboratory, the hope among biomedical engineering researchers is that its future use will result in treatment of human disease and illness. Doudna (2015) believes the time has come to engage in global conversations about the potential societal and ethical ramifications of using this technology on humans. She argues for researchers to consider all of the implications of doing so before the technology is approved for regular clinical use. What Doudna suggests in her talk is that the potential consequences of using gene-editing technologies should be considered now, since CRISPR-Cas9 has become clinically viable. Implied in her argument is a consequentialist ethical position that is a commonly taken approach by researchers who call for post-technological design ethical reflection. The focus is on consequences, or impacts, once the technology is already designed. Unfortunately, this call to action may already be too late in the development process to account for potentially negative consequences, as it becomes more difficult to change the design of a technology once it becomes regularly used within society.

The consideration of social impacts once a technology is developed deflects attention from the people who create and design these technologies. This perspective implies that a

technology is not a technology until it is used, which, in turn, supports the notion that technology is neutral until the moment of its use. Scholars in the areas of science and technology studies (STS) (Winner, 1980; Latour, 1987; Law, 1992) and values and design (Nissenbaum, 2009; Shilton, 2010: 2018a; Friedman, Kahn & Borning, 2013) fundamentally reject the presumption of neutral technologies. People create technologies and perform actions throughout the design process while situated within a broader socio political context. Technologies come to embody specific arrangements of power and authority that reflect human associations as well as activities taking place within these arrangements. This embodiment happens in two ways (Winner, 1980).

First, humans have values that shape their design practices, and technologies come to embody those values. This assertion draws attention to individuals and groups who are responsible for the development of a technology and accounts for how their politics shape their design practices. Second, the use of technology addresses a particular social issue. This suggests it is the consequences of how a technology is used that demonstrate its values and impacts on society. Both types of technological embodiment of values and politics matter within the context of novel biomedical technology design; however, the focus of this dissertation project is on the actors responsible for their development.

Nevertheless, what is meant by values, within the broad context of technological design, is inherently difficult to define. In this project, values are those factors (e.g., principles, standards) that are held in high regard and considered important. Values guide, justify, and explain attitudes, norms, opinions, and actions (Feather, 1985; Schwartz, 2007). Values within a technological context may be functional (i.e., technical elements or requirements of a system), or they may be those with moral import (Manders-Huits, 2011). Values such as responsibility, transparency, and wellbeing have a moral import based on what makes for right and wrong behaviors and actions. The use of ethical perspectives, such as deontological ethics, where the

morality of an action is based on the action itself, or consequentialism, where what makes for a morally right act is one that produces a positive outcome, can be used to justify these moral claims. The values associated with any technology are also composed of dimensions based on the source of that value (i.e., setting, environment, or context) as well as the attributes (i.e., quality or inherent characteristic) of those values (Shilton, Koepfler & Fleischmann, 2013; Shilton, Koepfler & Fleischmann, 2014). This conceptualization of values is used throughout the entirety of this dissertation.

The designers of novel biomedical technologies are university-based researchers who work in laboratory settings and are affiliated with departments of biomedical engineering. These laboratory groups are one part of the larger sociotechnical system in which novel biomedical medical technologies are designed. Sociotechnical systems dynamically bring together people in roles and in relationships with systems elements that include software, techniques, support resources, and information structures (Meyer, 2006; Kling, 2007). The technological developments of biomedical engineering laboratories are the result of sociotechnical interactions among technological systems, people, and values. This project accepts that people have values that shape their design practices and that resultant technologies embody these values. This serves as one of the main reasons why biomedical device engineering laboratories are at the center of analysis for this project. The values enacted within the laboratory research and development activities of biomedical engineers shape the way in which novel biomedical technologies are designed. The potential for biomedical engineering laboratory practices to result in novel biomedical technologies that implicate certain values, such as human wellbeing, should be questioned. Such an examination would uncover how laboratory practices implicate these values and suggest possible changes in the design process.

University-based biomedical engineering laboratories are involved in the initial design

stages of novel biomedical technologies. Assessments of the suggested value implications of early-stage laboratory design practices present the best opportunity to identify how and why ethical interventions should be integrated into the design process. Values and design scholars (Verbeek, 2008; Knobel & Bowker, 2011; Shilton, 2013; Friedman, 2017; Nissenbaum, 2017) argue that early and consistent interventions are needed within laboratory design practices. The implementation of ethical interventions is encouraged at earlier design stages based on the perception that is it easier to make changes to a developing technology at this point rather than at a later stage (Van der Burg & Swierstra, 2013; Van den Hoven, 2013). Although designers of technology do have more power to make adjustments earlier in the design process, they also lack the information needed to make those changes (Van den Hoven, Vermaas & Poel, 2015).

Olya Kudina and Peter-Paul Verbeek (2019) recently addressed this control dilemma within the context of Google Glass, the value of privacy, and a study of "morality in the making." They draw on the work of David Collingridge (1980), which asserts that changing technological developments is easy when their implications are not yet manifest, but once the implications are known, they are difficult to change. Referred to as the double-bind problem, the first issue is an information problem, where technological designers cannot easily predict the impacts of technologies until they are extensively developed and used. The second issue is a power problem, where having control or the ability to change a technology is difficult once its use becomes entrenched in society. The double-bind problem complicates the answer about when is the best time to insert ethical interventions in the technological design process.

One critique of ethics and technology research is that proposed interventions always seem to appear either too early or too late in the design process (Kudina & Verbeek, 2019). This dissertation project argues that this perception is both right and wrong and that the decision as to which is correct depends on the stage of development, not just of the primary technology at the

center of discussion but of other technological elements that also interact with or within that technology. Consider this claim within the context of novel biomedical technologies. The designation of "novel" alone implies that these technologies are new and present the ideal laboratory context in which to suggest the inclusion of early-stage ethical design interventions. The validity of this assertion, however, depends on the type of novel biomedical technology under development. Not all novel biomedical technologies, and not all of their included elements, are, in their totality, 100% new, original, or unusual in quality or result. The amount of true novelty associated with the developing technology depends on a variety of factors. These factors stem from where biomedical engineering laboratories are situated within the broader institutional context. This context for biomedical engineering laboratories is largely shaped by the principles of translational medicine.

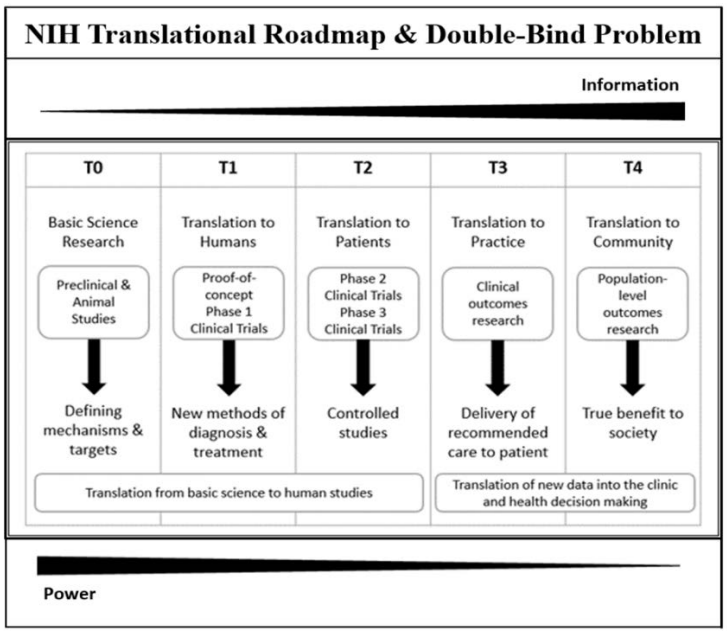


Figure 1
(NIH Translational Roadmap: Adapted from Liverman, et al., (2013))

In 2003, the NIH created a conceptually linear five-stage translational roadmap based on the principles of translational medicine, which provides a high-level depiction of the research and development practices of biomedical researchers (Figure 1). It also indicates the major

translational milestones associated with each stage. The stages along this roadmap implicitly mirror the normative progression of technological innovation. In this project, the double-bind problem is incorporated into the roadmap. This merging of concepts suggests that biomedical engineering laboratories encounter various design challenges based on the starting location of their research projects. This starting location depends on the type of novel biomedical technology designed in a laboratory. For example, biomedical engineering laboratories developing completely novel and new technologies are likely engaged in early-stage basic science research (stage T0). The laboratory works with a technological system of which no part has already achieved the final stage of translation (stage T4). However, biomedical engineering laboratories developing novel technologies in which some elements are already used clinically begin their research projects from a later stage of translation (stage T3). Within the context of the double-bind problem, early-stage laboratories arguably have more power to make technological changes than later-stage laboratories. Conversely, later-stage laboratories have more information on which to base technological changes. However, the decrease of one problem invariably leads to the increase of the other.

This dissertation examines the laboratory research and development activities of two groups of university-based biomedical engineers. This project uses a triangulation methodological approach; data were gathered using observations, interviews, and document analysis, and grounded theory was used to analyze this data. The technological design practices of biomedical engineers are considered within the context of the type of novel biomedical technology developed and where these activities situate themselves along the NIH translational roadmap. Additionally, the triple helix model of innovation is used to explore how values enactments and tensions manifest within laboratory environments. The findings of this study indicate how the laboratory practices of each group implicate specific values and consider the

potential ethical consequences of these practices and their values implications. Discrete interventions are suggested, and they propose ways to address issues of values and ethics within the biomedical engineering context. Interventions at both the laboratory level and the institutional level are recommended, and ethical theory is used to justify the associated moral claims.

1.2 Research Questions

Examination of the practices of university-based biomedical engineering laboratories is under-investigated in social scientific research. These groups are not often thought of as designers of technologies because their laboratory design activities happen at the earliest stages of development; they have little contact (i.e., visibility) with healthcare stakeholders; and the field of biomedical engineering is an emerging discipline. These factors make biomedical engineering laboratories a complicated yet compelling group of researchers to study. Little is known about how values manifest within their laboratory spaces and how these values ultimately impact the design of novel biomedical technologies. The potential values implications of these design practices need to be understood, as they have important ramifications for how these technologies will one day be used to treat patients. Additionally, university-based biomedical engineering laboratories, and the institutions that support their activities, must implement design interventions that address these values implications. The findings of the following questions are used to address these issues and to help fill this knowledge gap within values and design research.

1. How are values enacted within the research and development activities of university-based biomedical engineering laboratories, and how do they impact the design of novel biomedical technologies?
2. What are the suggested values implications of university-based biomedical engineering laboratory practices?
3. What values-based design interventions should biomedical engineering communities implement in support of the production of ethical biomedical technologies?

1.3 Contributions of Study

The contributions of this dissertation project address issues on both practical and theoretical levels. This section identifies four specific contributions of this study. First, the results of this project add to values and design scholarship by identifying how values play an important role within the research and development activities of biomedical engineering laboratories. Although previous values and design research considers values within laboratory spaces, especially of those groups designing information and communication technologies, little work considers this within the context of biomedical engineering. The findings of this dissertation project also support a social constructivist view of technological development versus a determinist perspective. Biomedical engineering laboratories are composed of people and social institutions who bring values into the design process and are not solely impacted by the use of technology. Moreover, this dissertation situates biomedical engineering laboratories within a sociotechnical context that is often used in values and design research as well as in social informatics. Making the sociotechnical context even more explicit provides a critical foundation to examine the values of biomedical engineering laboratories.

The second contribution of this study is that it finds that values implications of the design practices of biomedical engineering laboratories differ based on their starting location along the translational roadmap. The research and development activities represented on this roadmap reflect the stages of technological development. Values and design scholars argue for early values interventions into design processes, but they often struggle with the question: How early is too early? Part of the answer to this question depends on where a group is in the technological design process (even when designing novel technologies). For example, biomedical engineering laboratories engaged in basic scientific research (stage T0) are early-stage designers who develop novel biomedical technologies composed of entirely new or unique elements. Biomedical

engineering laboratories that develop technological elements intended for integration with clinically used technologies are later-stage designers (stage T3) along the roadmap. The laboratory practices of each type of biomedical engineering group differ because of their starting location within the translational process. This location also determines how, and to what level of influence, each type of laboratory interacts with the triple helix of institutional actors. These interactions directly impact the manifestation and enactment (i.e., process of acting something out) of values within laboratory settings (Mol, 2002). Therefore, they should also inform where and how values interventions should be implemented.

Third, most research about the ethics of biomedical technology focuses on one specific technology. For example, genetic engineering and nanotechnologies receive a significant amount of attention within the science and technology studies literature, but these examinations provide just one level of concentrated analysis of the social impact of this single technology. However, expanding the analysis to entire classes of biomedical technologies uncovers unique values and ethics insights. This project, for instance, makes an important distinction between the development of cell-based novel biomedical technologies and the development of device-based novel biomedical technologies. By comparing the laboratory design practices of these two broader, yet distinctly different, categories of novel biomedical technology, it is possible to uncover critical values implications. As one of the results of this study demonstrates, biomedical engineering is not a unified discipline. Instead, it is the attempt to merge the disciplines of biology and engineering, where each has its own history and values. The findings of this project suggest that each category of a biomedical engineering laboratory tends to align with one set of disciplinary-based values more so than the other. This alignment results in values tensions that are acted out in laboratory spaces. Proposed design interventions must consider these tensions and appreciate how they manifest within the broader institutional context.

The last contribution of this project is primarily theoretical in orientation. One critique of values and design studies is that they often avoid the use of theory to examine the values implications of different design practices and to justify their assertions Manders-Huits, 2011; Borning & Muller, 2012; Jacobs & Huldtgren, 2018). This criticism is especially pronounced for studies coming out of value sensitive design (VSD). The VSD approach advocates for the identification of values implicated within a particular design project, and it proposes that researchers consult a values heuristic (of 13 specific values) to determine which values may be implicated. The criticism of VSD is that these values implications are often presented without ethical justification. For example, when the results of a VSD analysis suggest that the design process of a project implicates the value of privacy, from what ethical orientation is this assertion made? Is the assertion based on a consequentialist perspective concerned about the potential use of the technology? Or is the assertion based on a deontologist perspective focused on the ethical duties of those responsible for development of the technology? In this dissertation project, ethical perspectives are used to ground moral claims related to identified values implications and suggested interventions. These interventions are based on ethical justifications, which provides a unique contribution to the theoretical aspects of a VSD approach.

1.4 Definition of Key Terms

Biomedical technology: The use of biological processes, organisms, or systems to produce products intended to improve the quality of human life. In this project, two categories of biomedical technologies are referenced: *novel systems* (cell-based technologies) and *novel applications* (device-based technologies).

Consequentialism: A class of normative ethical theories (e.g., utilitarianism) asserting that the consequences of an individual's conduct serves as the basis for any judgment about the rightness or wrongness of that conduct. What makes for a morally right act is one that will produce a positive outcome.

Deontological ethics: A normative ethical theory based on the claim that the morality of an action should be based on whether that action itself is right or wrong under a set of rules, or from a place of duty, rather than based on the consequences of the action.

Morality: Principles concerning the distinction between right and wrong and good and bad behavior. Morality also refers to a system of values and principles of conduct held by an individual or a group.

Responsibility: The state or fact of having a duty to deal with something or of having control over someone. In a globally connected world, new forms of hierarchy emerge with extended moral chains of responsibility, implying that actors have a new indirect duty of responsibility or a duty of care for others.

Sociotechnical system: The complex interdependent system of people in roles and in relationships with system elements, including software, techniques, support resources, and information structures.

Translational medicine: A framework within biomedical and public health research that aims to improve the health of individuals and the community by translating findings into diagnostic tools, medicines, and procedures. Translational medicine builds on basic research advances and uses them to develop new therapies or medical procedures.

Transparency: In behavior and actions, to operate in a way that is easy for others to see what actions are performed. In epistemology, the clarity of knowledge in the properties of epistemic states.

Triple helix model of innovation: Refers to the set of interactions between government, industry, and university that drive innovation. The model conceptualizes reciprocal linkages among these three groups of institutional actors.

Values: What someone judges to be important in their work or life. For example, responsibility, transparency, and wellbeing are types of societal values that may be held in high regard. These are values with *moral import* in how they relate to what is considered right and wrong within an ethical context.

Wellbeing: Human satisfaction with life; an evaluation of the general goodness of a state or event to the individual or community as a distinct moral or legal evaluation.

1.5 Organization and Summary of Chapters

This dissertation is presented in eight chapters. Chapter 1 presents a general introduction to the context of the study and identifies university-based biomedical engineering laboratories as sites of novel biomedical technology development. The concept of the triple helix model of innovation is briefly introduced, and the NIH's view of translational medicine is first presented. The problem statement that guides this dissertation is explored, and connections between design practices and technologies embodying politics are considered. The sociotechnical design context

of technological development is presented, and the social impacts of technological use serve as an entry point into discussion of values and design. The double-bind problem argues that there are design challenges when attempting to change the design of a technology based on how well its use is entrenched in society. Values and design scholars argue for early-stage ethical design interventions, but the need for ethical justifications to ground these interventions is made. This chapter also presents three research questions that direct this project. These questions seek answers related to implicit values active within biomedical engineering, the values implicated by laboratory design practices, and suggestions for ethical design interventions to combat these implications. Four primary contributions of this study are identified, and they are: the identification of value found within biomedical engineering laboratories as a function of a larger sociotechnical system; the values implications of two broad categories of novel biomedical technology; how implications vary based on a group's progression along the translational roadmap; and the ethically justified claims of these values implications and suggested interventions. A list of defined key terms is also provided, as is a description of how chapters in this project have been organized.

Chapter 2 provides a literature review of related research that serves to situate this project within certain intellectual domains and includes engagement with relevant scholars in the field. This work contextualizes scientific practice as a network of activities, where each element of the network is in perpetual relationship with other nodes, and nodes are composed of people and technology. Scientific laboratories are one place where these relationships act out. The activities performed within these spaces are influenced by several institutional actors, with the triple helix model of innovation identifying three of these actors as the university, industry, and government. Combined with the initial steps used to model a sociotechnical interaction network (STIN), these approaches can be used to identify a relevant population of system interactors for examination as

well as the core reactors (i.e., those groups found within the system of interactors that influence design practices) within scientific laboratories. Sociotechnical relationships are also complicated when university-based interdisciplinary scientific laboratories bring together the work practices of two (or more) different disciplines. Each discipline is rooted in its own cultural values, which impact technological design practices within the laboratory. The sources and attributes of these values differ between scientific disciplines and within a hierarchical context that values the epistemological commitments of certain disciplines over those of others. The resultant laboratory design practices suggest implications for values of moral import that speak to what makes for right and wrong behaviors. Ethical theories should be used when ethical interventions into the design practices of technological designers are proposed.

Chapter 3 describes the methods used to collect and analyze study data. Results are based on the research and development activities of 15 university-based biomedical engineering laboratories located at five R1[1] public institutions in the United States. A triangulation methodology was implemented, and data were collected using observation, interviews, and document analysis methods. More than 300 field-site observation hours were completed, 44 individual semi-structured interviews were conducted, and hundreds of pages of laboratory funding proposals, laboratory group websites, and academic department documents were analyzed. Data were analyzed using a modified grounded theory approach based on both *a priori* and emergent categories. Documents were coded using NVivo qualitative data analysis software, and significant themes were also identified and explored.

Chapter 4 is the first of three findings chapters included in this dissertation. It presents the results of applying step one and step two of a STIN modeling activity. These activities establish

[1] The Carnegie Classification of Institutions of Higher Education denotes levels of research activity by institution. The R1 designation stands for: very high research activity.

the identification of various incentives (i.e., step three of a STIN model) that are discussed in Chapters 5 and 6. Modeling step one found that both cellular biomedical engineering laboratories and biomedical device engineering laboratories are shaped by the same population of system interactors. These interactors include actors from government (funders, regulators, legislators), from industry (companies, manufacturers, publishers), and from university (colleges, departments, laboratories). Although these system interactors reflect the three main areas presented by the triple helix, system interactors from healthcare (hospital systems, clinicians, patients) also play a part in biomedical engineering practices. The laboratory activities of cellular biomedical engineering laboratories were found to be associated with those happening at stage T0 along the NIH translational roadmap, whereas the laboratory activities of biomedical device engineering laboratories were found associated with stage T3 practices along the translational roadmap. The relationship each biomedical engineering laboratory has with the stages of translation directly impacts the level of influence each core reactor group has on its technological design practices.

Step two of the STIN modeling activity found that cellular biomedical engineering laboratories are highly influenced by government funders and publishers. They are also moderately influenced by manufacturers, patents, and the FDA. The least influential are patients, industry funders, and clinicians. Biomedical device engineering laboratories are highly influenced by industry funders, manufacturers, and publishers; they are moderately influenced by government funders, patients, and clinicians; and they are least influenced by the FDA. The results of this analysis found the characteristics of cellular biomedical engineering laboratories to include developing cell-based technologies (novel systems), working in wet labs, being hypothesis-driven, being led by faculty with backgrounds in the life sciences, working with preclinical technologies, and being located upstream along the translational roadmap.

Characteristics of biomedical device engineering laboratories include developing device-based technologies (novel applications), working in dry labs, being data-driven, being led by faculty with engineering backgrounds, working with post-translational technologies, and being located downstream along the translational roadmap.

Chapter 5 is the second of three findings chapters included in this dissertation. The results indicate that the laboratory research and development activities of cellular biomedical engineering implicate the values of responsibility and transparency. Cellular biomedical engineers resist labeling their laboratory developments as technological developments. What is used within a laboratory environment is not considered a technology and only becomes so once used outside of this environment. This reasoning serves to prevent cellular biomedical engineers from identifying as designers of technology. This perception compromises their responsibility to design safe cell-based technologies for human use. Transparency into the knowledge used to build aspects of cell-based technologies also is diminished during the laboratory design process.

Cellular biomedical engineers are also found to identify primarily as scientists; however, their laboratories are housed within academic colleges of engineering. Although they are members of biomedical engineering departments, the dominant disciplinary-based value system in the department is focused on engineering values (e.g., application, utility). Cellular biomedical engineers come to internalize these values and seek to produce research outputs based on them. This translates into a desire to form industry partnerships and to develop outputs that are patentable and marketable. However, due to very little collaboration with actors within healthcare, cellular biomedical engineering laboratories ultimately focus more on the creation of products than on methods of clinical treatment. This changes the primary values structure from one concerned about healthcare to one focused on profits. This motivation to establish industry partnerships complicates the responsibility of cellular biomedical engineers to develop

technologies focused primarily on patient care. This motivation also entangles, and makes less transparent, the perception of who serves as the imagined end-user of novel cell-based technologies. Translational intermediaries (i.e., commercial entities, the FDA) become the de facto end users instead of patients who will be the actual end users of these novel biomedical technologies.

Chapter 6 is the final of three findings chapters included in this dissertation. The results suggest the laboratory and research and development activities of biomedical device engineering laboratories implicate the values of responsibility and transparency. Biomedical device engineers work with post-translational clinical biomedical devices and describe their work practices as optimizing or improving these devices. This depiction of their research and development activities instills a false sense of security that the alteration of biomedical devices results in technologies safe for continued use. This approach decreases the perception of responsibility to perform reflective laboratory design practices.

Biomedical device engineers also engage in design activities that transform complex biological processes into simplified abstractions. Developing data models and software programs provides a sense of control over physiological functions. Biomedical device engineers are more likely to self-identify as engineers, and these abstraction methods align with engineer-based values of working to solve and fix problems. These methods also reflect tensions based on the disciplinary hierarchy that values engineering over biology. They also reinforce the perception that biology is easier to learn than engineering, as the former simply requires memorization and the latter is about a "whole way of thinking." Abstraction methods act to minimize biological complexity and decrease the transparency biomedical device engineers need to maintain into understanding physiological phenomena.

Chapter 7 provides a discussion of the findings as they relate directly to answering the

first two research questions presented in Chapter 1. This study finds that examining the origins of how values develop within biomedical engineering spaces is critical to answering the first research question. To suggest values interventions (research question #3), the source of enacted values must be identified. The manner in which these values have emerged suggest different implications for the design practices of cellular biomedical engineering laboratories and biomedical device engineering laboratories. This is due in part to the relationship each type of laboratory has to the process of translation. Where laboratories are initially located (i.e., at the being of their research projects) along the translational roadmap is key to understanding how values impact their design practices.

Understanding the dynamics of this relationship helps to answer the second research question, and findings suggest the laboratory activities of each type of group implicates the values of responsibility and transparency. The laboratory actions of both cellular biomedical engineers and biomedical device engineers adversely impact their ethical responsibilities as designers of technology. The laboratory activities of cellular biomedical engineers work to obscure (i.e., make less transparent) what is meant by translation and impact, and the activities of biomedical device engineers decrease transparency into biological complexity. However, this is not to say that individuals, or even laboratories, are totally at fault for these implications. Laboratory design practices are the result of interactions among actors (including institutions) within the sociotechnical system of biomedical engineering. These findings suggest that design interventions (research question #3) must target both laboratories and institutions, as they are all actors within the same system.

Chapter 8 provides a summary discussion of the values implications found in Chapters 5 and 6, but does so to situate the ethical design interventions that follow. Interventions are suggested for both cellular biomedical engineers and biomedical device engineers as well as the

institutional forces that influence each groups' laboratory practices. Three ethical interventions are suggested for cellular biomedical engineering laboratories. The first is to explicitly refer to laboratory research developments as technological developments. Laboratory members should use this language within group meetings and while engaged in more informal conversations with their colleagues. Professional associations and departments of biomedical engineering should also adopt technology-based language when referring to cell-based innovations. The second intervention encourages researchers to use the term "translation" to emphasize the clinical provision of care instead of the manufacture of a product. Laboratories must establish connections with healthcare stakeholders who will keep the treatment needs of patients at the forefront of consideration during the design process. Healthcare stakeholders need to develop more presence within biomedical engineering spaces to help bridge knowledge gaps with biomedical engineers. The third intervention calls for the contextualization of patients as the imagined end user of novel cellular technologies throughout the entire design process. Laboratories must retain awareness of the physiological context of the technologies they design. Additionally, healthcare stakeholders can work with laboratories to help reflect on potential negative impacts that novel cellular technologies may suggest for patients.

Biomedical device engineering laboratories are presented with two ethical design interventions. The first is a call for greater reflection of the continued safety of core biomedical devices while developing novel applications. Reflective practices should be encouraged within laboratory spaces to ensure that the altered device remains safe for patient use. These practices also need institutional support from funding agencies, which should implement proper financial incentives to bolster reflective laboratory design practices. The second ethical intervention is the need to address the implicit devaluation of biology within the biomedical engineering discipline. Laboratories should include a biologist on their teams who will work to keep the physiological

context of proposed novel applications in mind. The discipline of biomedical engineering must include a biomedical engineering-appropriate physiology curriculum that addresses issues of technological compatibility. The discipline also should implement a version of medical ethics training that speaks to the role of biomedical device engineers as important actors in healthcare.

CHAPTER 2: LITERATURE REVIEW

The intellectual foundation of this project is built on a range of scholarship from multiple domains. The exploration of values in biomedical engineering laboratory practices requires the use of an interdisciplinary set of sources. Research from the sociology of scientific knowledge (SSK) provides a social understanding of science and scientific processes. Biomedical engineering laboratories are embedded in scientific contexts composed of laboratory spaces located in university departments that are funded by government agencies, so SSK research provides the backdrop in which to understand the practices of biomedical engineers. Scholarship critical of positivist depictions of science comes from science and technology studies (STS), which suggest that dynamic interactions based on power, cultural differences, and external influences all impact scientific practice. This dissertation accepts a constructivist understanding of scientific practice and examines how institutional influences shape the values of biomedical engineering practice. Laboratory ethnographies also come from STS literature, and findings suggest that norms and values differ between groups even when located in the same scientific discipline. Biomedical engineering laboratories do not share the same norms and values, even though they share members of the same discipline, and comparing different groups sheds light on how their norms and values differ.

This dissertation is also in conversation with social informatics scholarship and adopts a sociotechnical interaction network (STIN) perspective in the exploration of biomedical engineering laboratory practices. Biomedical engineering laboratories are dynamic sociotechnical systems composed of actors at both the local and institutional levels. The interactions among interdependent social and technical actors directly impact a group's values. Related to this is human computer interaction (HCI) and computer-supported cooperative work (CSCW) research, which introduces a formalized values and design perspective to the

conversation. Areas such as values in design (VID) and value sensitive design (VSD) provide a critical lens which to examine technological design practices. Specifically, VSD encourages the use of theory to account for values throughout the design process and with consideration of their impact on society. This dissertation project relies, in part, on philosophical literature on ethics to justify VSD-inspired values interventions. Lastly, this project brings in historical information about academic disciplines, as well as U.S. government reports about biomedical research, to round out the analytical context. This information serves to ground an analysis of biomedical engineering as an emerging inter-discipline, built on the norms and values of longstanding disciplines, and as it is situated within the broader context of biomedical research.

This chapter is presented in four primary sections. First is a discussion about scientific environments and practice that includes a presentation on positivist depictions of science. The Mertonian norms of science are presented, as is a discussion on the hierarchy of the sciences and on differences between basic and applied sciences. Earlier works on scientific practice assumed that Mertonian norms provided an accurate account of scientists' values; for instance, that Merton's norm of "disinterestedness" meant that scientists would act in selfless ways that would result in the receipt of rewards. Social constructivist criticisms of these normative accounts of scientific practice have since rejected these positivist assumptions. Constructivists challenge the notion that scientists value the pursuit of scientific truth above all else. Scientists are found to act out of self-interest and seek glory for themselves and for the institutions with which they identify. Scientific practices are oriented toward serving the power structures in which they are embedded and from which they receive recognition, resources, and power themselves. These criticisms of normative scientific practice provide the framework in which the values of biomedical engineering laboratory practices are examined throughout this dissertation. Central to this examination is the way in which disciplinary cultural differences contribute to values

tensions experienced in the laboratory.

The second section is about sociotechnical systems and how values are intrinsic components of these systems. This literature presents sociotechnical systems as an interdependent system of people in roles and relationships with system elements. One specific approach, sociotechnical interaction networks (STINs), is presented along with the steps to follow to map the STIN elements of a system. The first two steps of this activity are applied in Chapter 4 to map the relevant system of interactors, and to identify those interactors that influence design practices (i.e., core reactor groups) relevant to biomedical engineering laboratories as STINs. Included in this discussion is how to identify and locate values dimensions within these networks by determining the source (i.e., setting, environment, or context) of those values as well as the attributes (i.e., inherent characteristics) of those values.

Emphasizing and making visible the centrality of values dimensions to the design process differs from standard technological design approaches that do not explicitly address values. Two specific approaches, values in design (VID) and value sensitive design (VSD), are explored with an eye toward how they introduce a values perspective into the design process. This dissertation project aligns with VSD in support of examining values with moral import, which are values associated with right and wrong behaviors and actions. This project also supports a VSD perspective by using ethical frameworks to justify moral claims. Ethical theories and perspectives are also presented and are used to justify the ethical values interventions suggested in Chapter 8 of this dissertation.

The third part of this chapter provides a discussion about U.S. institutions of science and technology. This section provides a framework for understanding the political economy context in which biomedical engineering laboratories operate and the effects this context has on shaping their values. This includes looking at the change in relationships among government, university,

and industry entities since World War II. Values in support of private property and free-market capitalism increased institutional influence on scientific research practices at institutions of higher education, while legislation, such as the Bayh-Dole Act, appeared to address some of the resultant tensions from these changes. Scholars introduced the triple helix model to conceptualize reciprocal linkages among the three institutional actors of government, university, and industry as they drive technological innovations. In this project, university-based biomedical engineering research is situated within the context of this theory and the institutional actor of the NIH is introduced. Specifically, NIH's five-stage roadmap of translational medicine is presented to establish the background in which to examine the technological development activities of biomedical engineering laboratories.

Lastly, this chapter concludes by first providing a brief history of biomedical engineering as an academic discipline. Understanding the historical context in which this discipline emerged helps to grasp its institutional foundations, its relationships to its parent disciplines, and its values development from these disciplines. All of these factors present the societal imperatives in which biomedical engineering has responded. This begins with a discussion of how engineers in the 1930s and 1940s worked to combine electrical systems and physics into their design of medical technologies. By the 1990s, revolutionary changes in biomedical technology and information brought unprecedented attention to the role of biology within engineering. However, as more biomedical engineering departments were established throughout the country, they were located in colleges of engineering. Attempts to merge biology and engineering into the interdisciplinary area has resulted in values clashes between these two groups, because each discipline differs in its laboratory work practices, the theories and methods used, and the notion of what should serve as a product of scientific knowledge. These values tensions establish a default position where the engineering perspective plays a dominant role and views biology as a domain to be exploited to

maintain its higher rank in the scientific hierarchy.

2.1 Scientific Environments and Practice

The scholarly examination of scientific researchers and scientific practices is a field of inquiry with a well-established history. Early works highlighted the social aspects of scientific activities while also accepting a positivist account of this work. Social constructivists criticize this depiction and argue that scientific practice is based on a network of activities infused with power and motivated by self-interest. This network takes on unique properties when the academic context of scientific practice is also considered. Disciplinary cultures have their own set of norms and values that result in value clashes and shape scientific activities.

2.1.1 Scientific Positivism

Robert K. Merton (1942; 1973), an early sociologist of science, helped lead the way for the use of a sociological approach to examine scientific processes from a social perspective. Merton was one of the first scholars to suggest that certain norms[2] and values could be attributed to science and scientific practitioners based on their professional affiliations. Merton argues that scientists function within an "ethos of science" based on a complex set of values where their work as professionals are shaped by various norms. Merton identified four norms (Figure 2) that he believed are binding to scientists and the goals of science.

Mertonian Norms of Science

Norm	Definition
Communalism	Common ownership of scientific discoveries; scientists give up intellectual property.
Universalism	Claims to truth are evaluated by universal or impersonal criteria, not on the basis of gender, race, class, age, religion, or nationality.
Disinterestedness	Scientists are rewarded for acting in ways that outwardly appear to be selfless.
Organized Skepticism	Ideas must be tested and are subject to rigorous and structured community scrutiny.

Figure 2
(Adapted from Merton, 1973)

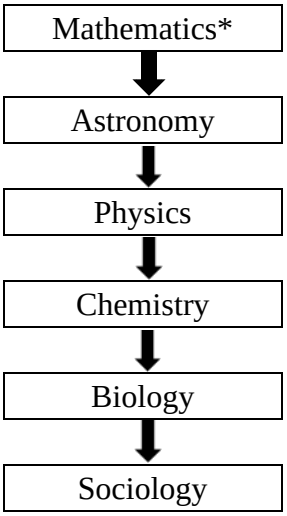
[2] Where "norms" are defined as those things that are usual, customary or standard.

According to Merton, these norms are not only inherent to the institution of science but also represent the values to which individual scientists ascribe. Mertonian norms imply that scientists value the pursuit and advancement of scientific truth above all else. For instance, communalism suggests that scientists value the advancement of science toward truth versus hoarding scientific discoveries for their own promotion. Another example is the norm of organized skepticism, which also assumes that scientists will humbly accept proof that their own claims are wrong (even if it damages their reputation) because the pursuit of truth is valued more than personal glory.

Merton's norms align with the positivist views of science as an enterprise committed to objectivity and neutrality (Panofsky & Calhoun, 2010). The positivist view also tends to divide scientific disciplines into those that are "hard" and those that are "soft." A hard science is one defined by its rigor, where the rigor of the discipline directly correlates to the extent that mathematics is used within the science itself (Storer, 1967). For example, physics is considered a hard science, heavily dependent on math in its methods, whereas sociology is regarded as a soft science and may use a variety of quantitative and qualitative methods to prove its knowledge claims. This division between hard and soft is also based in part on the long standing belief among researchers that there is a hierarchy among the disciplines. French philosopher Auguste Comte (1855) suggested that the sciences progress through ordained stages of development and do so at very different rates. This hierarchy is based on the complexity of the phenomena studies and the stages of their intellectual development (Cole, 1983). Comte focused on the empirical sciences in his depiction, as these areas are thought to differ in their degree of empiricism[3] (Conant, 1950), shared theoretical structures, and methods of consensus (Kuhn, 1970).

[3] In the traditions of John Locke (1689) and David Hume (1740), empiricism is a theory which states that knowledge come from sense-based experiences and emphasizes the role of empirical evidence in the formation of ideas rather than innate ideas or tradition.

Hierarchy of the Sciences



* Not included in Comte's original hierarchy

Figure 3

(Adapted from Cole 1983; Simonton, 2018)

Contemporary depictions of the hierarchy of the sciences often include mathematics and place it at the top (Figure 3). Mathematics was not originally included in Comte's hierarchy because it is nonempirical, is said to focus on "pure logic of truth," and is used to falsify hypotheses (Simonton, 2018); however, the discipline now serves as the perceived foundation for much of scientific practice (Cole, 1983; Simonton, 2018). Key to any hierarchy is the assertion that what is at the top has the most status or authority. In this case of scientific disciplines, mathematics now serves as the ultimate source of truth and knowledge. Disciplines are ranked lower on the hierarchy, in turn, have less status and less authority when it comes to making claims about truth and knowledge. They also have less access to societal resources to pursue their work (i.e., "harder" sciences tend to be better funded). The perceived rank of a discipline may influence how value clashes within and between disciplines ultimately are settled.

Positivist depictions of science and scientific disciplines also divide research activities by those focused on basic research and those focused on applied research. Basic research (also

known as basic science) is focused on general knowledge about nature and its laws and is performed without thought about its practical ends (Slaughter, 1993), whereas applied research (also known as applied science) is about the application of existing knowledge to practical applications such as technology or inventions (Roll-Hansen, 2017). This conceptualization of scientific activities implies knowledge gained via basic scientific methods will then advance along the continuum and be used to fuel innovations within the applied sciences. This normative view of scientific practice infers a gap between the basic and applied that must be bridged (Stokes, 1997; Vernig, 2007; Cagan, Justice & Tidmarsh, 2013).

In *Pasteur's Quadrant* (Stokes, 1997), a quadrant model of scientific research (Figure 4) marks a distinction between areas of research that focus on fundamental understanding about the world (i.e., its nature and laws), and research concerned with the use of knowledge to achieve applied goals. The Mertonian view of science equates to "pure basic research" that suggests other types of practice (i.e., those outside this quadrant) are not Mertonian in their norms and values. This model is used to help distinguish perspectives within the sciences and argues for the better utilization of scientific knowledge and research practices in the mission to actualize successful innovation. In other words, scientific practice outside the basic research quadrant is instead driven by the perceived utility (i.e., application to society) of that research.

Quadrant Model of Scientific Research

		Considerations of use? No	Considerations of use? Yes
Quest for fundamental understanding? Yes	Yes	Pure basic research	Use-inspired basic research*
Quest for fundamental understanding? No	No		Pure applied research

* Where Pasteur's research is located

Figure 4

(Stokes, 1997)

2.1.2 The Social Construction of Science

Scholars have since emerged who criticize the type of positivist views of science reflected in these divisions among disciplines (Mason, 2001; Berkhout, et al., 2007; Tijssen, 2010; Crandall, 2019). High-level positivist views of science and scientific practice obscure the complexities of science in action as it happens within laboratory environments and among various types of actors (Latour, 1987). For instance, ethnographic studies of scientific laboratories (e.g., Latour & Woolgar, 1979) have found that a scientist's pursuit of additional resources and prestige directly shape the content of scientific knowledge produced by the laboratory. Findings such as these support the criticism of Mertonian norms as reflecting stereotypes of what scientists should do in their practices versus what they do in actuality. Norms and values vary by context (Nissenbaum, 2009) as do the scientific practices associated with these environments. Positivist frameworks of science do not recognize the subjective and socially constructed elements at play within scientific laboratory practices.

STS scholars such as Michel Callon (1984; 1994) and Bruno Latour (1987) developed actor network theory (ANT) to argue that science should be thought of as a *network* of activities that includes not only the production of knowledge and texts but also comprises equipment, machines, computers, and skilled bodies. Each element within the network can be thought of as a node that is in perpetual relationship with other nodes, with their relationship (and the overall network) in constant making and remaking (Latour, 2005). ANT scholars reduce scientific practice to power games among actors pursuing their own interests (and their own power), which stands in contrast to the Mertonian norm of disinterestedness.

In a challenge to the positivist depiction of scientific methods as objective and working to reveal the true nature of the world (Merton, 1942; Popper, 1959), the social constructivist view of scientific knowledge production asserts that science is carried out in conjunction with people

and their environments and not in spite of them (Brown, Collins & Duguid, 1989). The process is not only about the use of evidence and reasoning to arrive at truth claims, it is also about the interactions among actors throughout the entire scientific process to arrive at these claims. For example, the results of an experiment performed by a researcher might be presented to other members of the laboratory group using data and graphs. This information may be interpreted differently by members, who then debate what it means, what is right or wrong, what is good or bad, and what should be done differently next time. Debates such as this also take place between different laboratory groups within the same scientific discipline. Conflicting knowledge claims are adjudicated and resolved not by examining the evidence or by conducting further experiments, but through social interactions. Ultimately, what is believed to be true is the result of social interactions as well as cognitive processes (Gieryn, 2010).

Bruno Latour and Steve Woolgar (1979) are often credited with performing the first laboratory ethnography using anthropological methods in their classic text *Laboratory Life.* In this study, they found that scientific work practices are based on complex relationships between routine lab practices and other activities performed by scientists in a laboratory environment. Scientists not only conduct laboratory experiments but they also engage in practices such as publishing, applying for grants, and working toward tenure. Latour and Woolgar refer to a cycle of credibility where scientists actively work to convert investments (e.g., money, grants, equipment) into forms of knowledge production (e.g., articles, data, arguments) that result in recognition within the field. Latour and Woolgar demonstrate that scientists prioritize factors such as career status, professional prestige, and the desire to secure funding to maintain and grow their laboratories.

In a study of high-energy physics laboratories, Sharon Traweek (1988) found that informal and cultural rules govern how laboratory researchers pass from one career stage to the

next. A power dimension is involved in this process that junior researchers must learn to navigate if they wish to advance to the next career stage. For example, in the case of short-term postdoctoral researchers, Traweek argues that they encounter expectations to engage in cooperative laboratory group work while, at the same time, they must make a name for themselves. Although somewhat already enculturated into the characteristics and norms associated with high-energy physics (as evidenced by successful achievement of earning the Ph.D.), they are still learning the informal rules of competition required to advance within the field. However, if they wish to advance to the next career stage, they must do what is needed to make a name for themselves. Traweek's findings echo elements of what social psychologist Theodore Newcomb (1943) asserts as the socialization hypothesis within the culture of higher education, where the beliefs and attitudes of students are influenced as a part of their academic experience. Scientific laboratories are filled with students who are learning the critical habits of the mind (Lipset, 1982) and establishing relationships between the attitudes and beliefs associated with the discipline and their professors (Dey, 1996; Andersen, 1999; Elchardus & Spruyt, 2009). Those who pursue a particular course of study experience a socialization process that prescribes a type of code of cognitive conduct (Guimond, Begin & Palmer, 1989).

2.1.3 Disciplinary Differences and Divisions of Science

Disciplines are a collective of people who have the same set of standardized intellectual interests; they are organized into units that grant degrees and powers to others (i.e., students) who are also a part of the collective (Turner, 2000). Although the history of how disciplines emerged is not fully agreed upon (Brinkmann, Jacobsen & Kristiansen, 2000), there are some general characteristics that define an area of intellectual pursuit as an academic discipline. The following six attributes may be used to identify a discipline (Krishnan, 2009): It has a particular object of research (e.g., law, society, politics), has a body of accumulated knowledge, has unique

theories and concepts, uses specific terminologies and language, has specific research methods, and has some sort of institutional manifestation in the forms of subjects, departments, or professional associations. Disciplines themselves, however, are not fixed nor static entities.

New disciplines can emerge as areas of knowledge grow and expand, with some of the growing communities associated with a particular area beginning to carve out new disciplines based on their professional needs. For example, within engineering, growing subspecialties (e.g., mechanical, electrical) within the labor force contributed to increased demand for formalized educational programs to train workers (Garrison, 2018). However, not all new disciplines are established in response to market needs. Other rationales may be the result of values clashes between researchers within a discipline. The rise of qualitative methods within the social sciences, for instance, continues to serve as a source of tension in many disciplines (Brinkmann, Jacobsen & Kristiansen, 2000). One response to this tension in the late 1960s and early 1970s was the movement among academics to establish new disciplines (e.g., women's studies, ethnic studies) that valued personal experience as a valid research method (Arthur, 2009). The decision to establish a new discipline based on values conflicts also speaks to the cultural tensions experienced by members of different disciplines.

Decades of study into differences among academic disciplines have found that different areas have their own distinctive cultural characteristics (Bailey, 1977; Clark, 1983; Traweek, 1988; Becher, 1989; Becher, 1994; Hofer, 2000; Calvert & Fujimura, 2011; Ma, et al., 2017), where, from an anthropological viewpoint, culture is defined as the traditional and social heritage of a people, including their customs, practices, transmitted knowledge, beliefs, morals, and linguistic forms of communication and meanings they share (Bailey, 1992). Academic disciplines demonstrate similar cultural characteristics from which the cognitive aspects of a discipline and their cultural aspects are inseparably intertwined (Becher, 1994). The

interconnected character of disciplinary cultures shapes epistemological assumptions and influences the thinking and reasoning process (Kitchener, et al., 1993). Differences among disciplines reflect and reinforce certain epistemological assumptions (Baronov, 2012), and they inform an individual's epistemological commitments, including how an individual comes to know, the theories they hold about knowing, and the manner in which epistemic premises influence cognitive processes (Hofer, 2000).

Cultural value tensions and clashes may also exist within a discipline even if researchers share the same research methods. For example, university-based scientific laboratories share many of the same cultural elements. A laboratory is led by a faculty member who directs the overall research trajectory of a group of researchers. These researchers are composed of postdocs and doctoral students, each of whom follows a particular career path and has related expectations. The members of the laboratory (including the faculty leader) engage in publishing practices (e.g., write and submit articles), present findings at conferences, and depend on funding from extramural agencies (both private and public) to support their research.

Scientific disciplines often vary considerably in terms of their norms and values. In *Epistemic Cultures,* Karin Knorr-Cetina (1999) challenges the notion that there is a unified science, one where the same norms and values are shared among researchers across disciplines. For example, she found that high-energy physicists rely more on cooperation among group members than do molecular biologists. This indicates that one field places a different value on the role of hierarchy in the construction of knowledge produced by their laboratory. These relational differences among group members reflects (and, in turn, impacts) the cultural values within each scientific discipline. They demonstrate how power dynamics and value clashes act out in the discipline itself.

Scholars of ANT argue that power relationships are best understood as a result of

network effects as they flow through the system (Law, 1992). Scientific networks present a collection of processes where individuals are enrolled into a particular way of knowing and conducting scientific activities. For example, if we consider Latour and Woolgar's cycle of credibility, we see collecting money, grants, and equipment as something that has value, because if a scientist converts these into knowledge (e.g., publications), they earn recognition in the field. The norm is that these investments and forms of knowledge production should be valued because they produce recognition, which translates into credibility, which translates into power within the community. Accumulating power is highly valued because it likely leads to even more grants, more publications, and more credibility given (by others outside of the laboratory) to the knowledge produced by a particular laboratory.

These power relationships are also found within individual laboratories and among members. Within scientific areas that feature the stages of career projection highlighted by Latour and Woolgar (1979) and Traweek (1988), a type of hierarchy[4] forms among laboratory members. These types of laboratory group hierarchies result in those individuals with the most authority having a larger influence on what scientific information ultimately is certified as the truth (Gieryn 2010). For example, after a laboratory group member performs an experiment, they often present and discuss the results with other members of the lab. Each individual of a group brings their own viewpoint regarding the information, so as the group debates the meaning of the results—and if tensions arise among members—it is likely that the viewpoint of the member with the most authority (i.e., power) will win out. Should a group of interdisciplinary scientists debate findings and experience such tensions, it is possible that the researcher associated with a

[4] If we think of a university-based scientific laboratory, this would place a Principal Investigator at the top of the hierarchy and the person with the most power. The next most powerful person would be a post-doctoral researcher, and below that person would be a graduate student.

higher-ranking scientific perspective may have more leverage. The laboratory's principal investigator (PI), for instance, often has the most power since they control the money. PIs define the research agenda and the methods that other laboratory members must follow. These activities among group members result in the construction of facts on behalf of those who are performing the science (Latour, 1987; Law, 1992), where the hierarchical nature of laboratory group work serves as an example of how network effects result in power relationships among actors and influence what counts as fact.

In the next section, a sociotechnical approach to understanding scientific practices is considered, specifically, using a sociotechnical interaction networks (STINs) framework. This framework accepts how ANT conceptualizes power relationships within networks and also supports Knorr-Cetina's (1999) assertion made in *Epistemic Cultures*, that scientific practice is made up of not only power relationships but is also shaped by cultural influences.

2.2 Sociotechnical Systems: Values, Design, and Ethics

Scientific laboratory research and development activities involve a complex set of interactions between social and technical elements. Contextualizing these practices as sociotechnical interaction networks enables the identification of actors in the system that contribute to value manifestations and enactments. Locating and identifying the sources of and attributes of values within these networks provide a way to consider their implications and to evaluate potential ethical interventions.

2.2.1 Sociotechnical Interaction Networks

Information scientist Rob Kling spent much of his career focused on the development and study of the field of social informatics. It is defined as "a body of research that examines the social aspects of computerization" (Kling, 2000) and is concerned with the design, uses, and consequences of information technologies that takes into account their interaction with

institutional and cultural context (Kling, 2007). Central to the field of social informatics is the concept of sociotechnical systems,[5] which refers to the complex interdependent system of people in roles and relationships with system elements, including software, techniques, support resources, and information structures (Meyer, 2006; Kling, 2007). One analytical framework to emerge from this scholarship is that of sociotechnical interaction networks (STINs). Drawing on theories from STS, including the social construction of technology (SCOT) (Bijker, Hughes & Pinch, 1987), and actor network theory (ANT) (Latour, 1987; Law, 1992), a STIN approach focuses on a network that includes people (including organizations), equipment, data, diverse resources (money, skill, status), documents and messages, legal arrangements and enforcement mechanisms, and resource flows (Kling, McKim & King, 2003). This approach provides a way to understand sociotechnical systems by mapping relationships between elements of the system where neither the social nor the technical is privileged over the other (Meyer, 2006).

Eight Steps for Modeling a STIN	
1.	Identify a relevant population of system interactors
2.	Identify core reactor groups
3.	Identify incentives
4.	Identify excluded actors and undesired interactions
5.	Identify existing communication forums
6.	Identify resource flows
7.	Identify system architectural points
8.	Map architectural choice points to sociotechnical characteristics

Figure 5
(Kling, McKim & King, 2003; Meyer, 2006)

Although a STINs approach has been critiqued as not quite a methodology (Meyer, 2006; Suri, 2011; Kreeger & Harindranath, 2017) and not quite a theory (Walker, 2009; Beamer, 2019), it has been proven analytically useful in mapping complexities inherent between network relationships and system elements (Figure 5). Information scientist Eric T. Meyer (2006)

[5] A term first coined by Eric Trist, Ken Baforth, and Fred Emergy based on their work while at the Tavistock Institute in London. See: (Trist & Bamforth, 1951; Emery & Trist, 1965).

suggests thinking of STINs as a strategy, that—when using a list of steps (Figure 5) initially identified by Rob Kling, Geoffrey Martin, and Adam King (2003)—can be used to map system elements and relationships among elements.

Although listed in sequential order, both Kling and Meyer assert that these steps should be thought of as illustrative and not enumerative. The first three steps are of particular significance to this dissertation project. For example, step one is to identify a relevant population of system interactors. These are the actors that comprise a particular sociotechnical system and that interact with each other on some level. This step is about attempting to identify the likely actors involved in a system and, to some extent, draws a boundary as to which system elements do and not belong in a particular sociotechnical system under examination. Step two attempts to identify core reactor groups that belong to various categories of system interactors. Core reactors result in actions and interactions between elements of the system and have varying levels of influence over behaviors (i.e., design practices). Step three is about the identification of incentives that are presumed to shape behavior. Values are an inherent part of any STIN, and implicit in this step is that, by identifying incentives, one can understand and account for actors' behaviors. STIN approaches have been successfully applied to other studies of scientific laboratory practices, including a study of scientists working at the National High Magnetic Field Laboratory in Florida (Burnett, G. et al., 2014) and a study of marine biologists switching from analog to digital photographic formats (Meyer, 2007).

Adopting a sociotechnical systems approach provides recognition that scientific practices are contextual and that activities are distributed across systems of interaction with persons, artifacts, instruments, and traditions (Osbeck, et al., 2011). All of these system elements are actors that exert influence and dynamically work together within the network (Pinch & Bijker, 1987). The STINs modeling strategy enables the mapping of actors and their interactions within

the context of a particular sociotechnical system. This process makes explicit the core actors, stakeholders, resources, and design choice points within the system. Combining a values-aware approach with a STINs strategy also facilitates the mapping of different values associated with the system. Identifying and locating values within a STIN enables a deeper and more nuanced understanding of how values manifest and are enacted within these dynamic contexts.

2.2.2 Identifying and Locating Values

When a group of individuals come together to design a technological system, their values and the context (i.e., institutional and technological) in which those values manifest shape the way that system is built. Scholarly examination of the relationships among technological systems, people, and values is inherently difficult and complex. For instance, what exactly is meant by values? In the broadest sense, values are those factors (e.g., attributes, principles, standards, and so on) that are held in regard and considered important or worthy (Hester, 1996). What happens when differing values clash within a particular context? Whose (and which) values take precedence? When we examine a sociotechnical system, we find values as they are negotiated and enacted among people, technologies, and institutions (Shilton, Koepfler & Fleischmann, 2013). Values guide, justify, and explain attitudes, norms, opinions, and actions (Feather, 1985; Schwartz, 2007), and they serve as central to our understanding of social behavior (Rokeach, 1973).

Some values and design scholars (Le Dantec, Poole, & Wyche, 2009; Jacobs & Huldtgren, 2018) with a focus on sociotechnical systems argue that the values and design field needs more directed approaches to determine when, where, and what values are associated with a particular system. Identifying the *values dimensions* of a system (Shilton, Koepfler & Fleischmann, 2014) is one way in which researchers can implement a more formalized procedure. This approach suggests which research methods work best to identify different

sources (i.e., setting, environment, or context) (Figure 6) of particular values as well as the *attributes* (i.e., quality or inherent characteristic) of those values (Figure 7) (Shilton, Koepfler & Fleischmann, 2013). The sources of values within a sociotechnical system are those that relate to the unit, assemblage, and agency. The attributes of those values within a design context reference the dimensions of salience, intention, and enactment.

Dimensions Describing Sources of Values

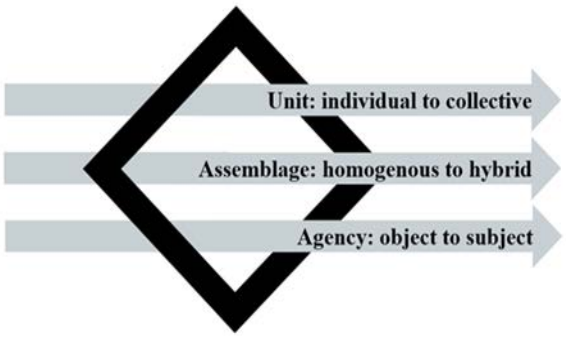


Figure 6

Dimensions Describing Attributes of Values

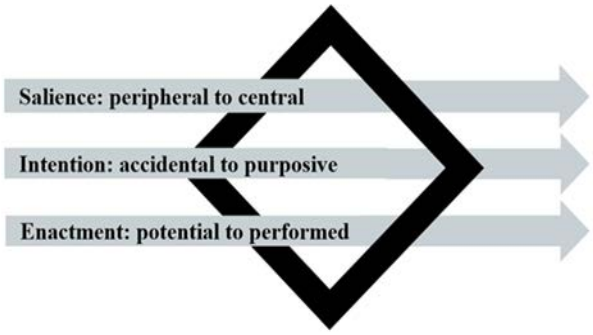


Figure 7

(Shilton, Koepfler & Fleischmann, 2013; 2014)

The sources of values are key to the identification of specific values present within a particular context. The unit dimension of a value source considers the spectrum of values held by individuals to those shared by a collective group of people. Points along the spectrum may refer to the values of individuals, work groups, institutions, and society (Shilton, Koepfler & Fleischmann, 2013). Individuals are located at one end of the spectrum and may reference designers, or users, a technological element, or even a stakeholder. Located at the other end of the spectrum are collective values that represent the goals embedded in a particular sociotechnical context. Collective values speak to the norms of a group as they relate to actors serving in particular roles and when engaged in certain activities.

Another source of values relates to the dimension of assemblage. This source speaks to the bringing together of various types of actors and the extent to which they share attributes (i.e., homogeneous) or diverge in their characteristics (i.e., heterogenous). Sociotechnical systems

combine a diverse set of actors, both social and technical, so it is important to recognize where and how actors share or differ in their characteristics. These characteristics tell part of the story of where values originate and may vary from the personal to the educational to the technical. For example, an interdisciplinary group of scientists may differ in their educational backgrounds but share the experience of working with a particular set of laboratory materials (e.g., microscopes, spectrometers). This may translate into a shared value, for instance, that of trust, regarding the quality of knowledge that results when working with these materials. However, the more heterogeneous a collective, the more the need to discover value sources increases. Consider again this group of scientists who have different educational backgrounds. Chemists may use the same laboratory materials as biologists, but if the focus of the project is on cellular behavior and not on chemical reactions, for instance, the chemists might not share the same level of concern (i.e., the same value) for questionable cellular behavior, and they might ask different questions about why this questionable behavior is happening than a biologist would. These value clashes extend from the initial sources that shape these values.

The final source dimension of values is that of agency, which refers to the degree to which objects and subjects have choice and the ability to possess and express values (Shilton, Koepfler & Fleischmann 2013; Shilton, Koepfler & Fleischmann, 2014). For example, a group of designers have agency as subjects where they can choose to have certain values, whereas an object such as a flash drive or computer screen has its values assigned to it by the subject. Agency also is found along a spectrum as with the other source dimensions described here, specifically where subjects—such as designers, for instance—can be treated in some contexts as objects. Shilton, Koepfler, and Fleischmann (2014) present autonomous machines as an example of where an object may be studied as a subject with its own value agents.

The attributes of those values found associated with certain sociotechnical systems also

have dimensional characteristics to consider. The dimension of salience considers the importance that stakeholders have for values along a spectrum from peripheral to central (Shilton, Koepfler & Fleischmann, 2013). The centrality of a particular value depends on the stakeholder and on the context. For example, if a scientific laboratory designs a novel technology, a commercial entity may value the marketability of that technology more so than does a user who is also a stakeholder in this context. Additionally, peripheral values are important, but they do not serve as the primary drivers of particular values, yet their influence is still felt within that context.

Another dimensional attribute is that of intention and the degree to which designers mean to enact a particular value. For example, in 1991, the U.S. Congress lifted the ban on women flying aircraft in combat (Schmitt, 1991). However, as women sought training to become military pilots, it was found that more than 70% of female recruits were considered ineligible to safely fly the military aircraft (Weber, 1997). The reason is that the physicality associated with being female did not align with the design of the cockpit, which was based on male specifications related to height, weight, and strength (Binkin, 1993). Although the intention of the original aircraft designers was not the overtly sexist exclusion of women, their design did result in an accidental value expression reflective of the patriarchal values inherent in the military culture (Enloe, 1983; Cooke & Woolacott, 1993; Enloe, 2017; Henry, 2020). This is an example of how a value could be expressed accidentally, as the intention of the design was not the explicit exclusion of female combat pilots.

The final attributes of values dimension is enactment, which refers to the degree to which a system brings a value into being (2013). Actors and elements in a system may have the potential to display particular values, but the potential to enact certain values is not the same as the actual enaction of those values. For example, until a female pilot attempted to fly the military aircraft for which the cockpit was designed based on male measurements, the sexist value had

not yet been enacted. The same may be true for the designers of the system as well. They may have the potential to bring certain values to the design process, but it is not a guarantee that these values will be enacted within a particular context.

This chapter has thus far explored the benefits of adopting a STINs strategy and applying a values dimension approach in the study of sociotechnical systems design. The values dimension approach forms a useful basis for action on values in design. Identifying the source of where and how values form is critical for successful interventions. For instance, does the individual researcher hold a particular value, or does the laboratory culture support a certain value? Who does and does not have more or less agency to implement any changes within the laboratory? Addressing values attributes is also essential; for example, the dimension of intention could be used in helping biomedical engineers as designers of technology become more aware of the values they unknowingly hold. Design interventions could be used to help biomedical engineers become more intentional in how their values shape design practices by making the values they hold more explicit. The next section provides a closer examination of how a values-aware approach challenges normative design practice.

2.2.3 Design Practices and Values and Design Perspectives

The assertion that values influence how a technology is created stands in contrast to commonly held views of what constitutes design. From the common viewpoint, the process of design results in the development of a plan or specification for the construction of an object or system (Visser, 2006). It is performed by designers (i.e., individuals or groups) who follow a sequence of design activities, use various methods, and do so to meet specific design goals (Cross, 2001). Although this process is conducted by people and for people, the design process in various design-based disciplines (e.g., computer science, engineering) is thought of as a technical and value-neutral task focused on the development of artifacts that meet functional requirements

by clients and users (Van den Hoven, 2013). This perspective, however, removes the social and cultural context in which this process takes place.

In a study of an internet architecture engineering team working on the named data networking (NDN) project, Katie Shilton (2015) found that engineers make technical choices while also weighing nontechnical values. For example, she found that the engineers wanted to create an efficient and dynamic internet architecture, yet they also wanted a system that would protect the personal liberties (e.g., privacy, security) of potential future users. This group of designers (i.e., the team of engineers) were forced to make a choice between functional values and values of moral import (Manders-Huits, 2011). Values such as privacy and security speak to what is important to individuals and society. Within the context of design, it is about creating technologies that make lives better and improve human wellbeing (Manders-Huit & Van den Hoven, 2009). Values of moral import are based on what constitutes right or wrong behaviors and actions (Hester, 1996). The way in which technologies support or inhibit what is right or wrong demonstrates their inherent political qualities.

Two critical points should be drawn from research about technology and politics. The first is that individuals and groups refer to and depend on a variety of values (i.e., functional, social, moral) throughout the entire technological design process. These values inform their work practices, including setting priorities, engaging activities, performing methods, and achieving design goals (Schwartz, 2007). The second point is that values are impacted through the use of technology, and their use impacts the values of moral import that we hold as members of a collective body of people. Scholars from the areas of values in design (VID) (Nissenbaum, 2001; Flanagan, Howe & Nissenbaum, 2005; Knobel & Bowker, 2011; Nissenbaum, 2017), and value sensitive design (VSD) (Cummings, 2006; Manders-Huit & Van den Hoven, 2009; Friedman, Kahn & Borning, 2013; Milchram, et al., 2018) argue for the importance of using theoretically

grounded approaches to the design of technology that account for values throughout the design process and with consideration for their impact on society.

Helen Nissenbaum (2017) describes VID as the systematic study of sociotechnical systems to discover, analyze, and operationalize values within the context of particular design projects. The focus is explicitly on the designers of technology, and VID scholars argue that it is insufficient to consider how technologies are used to assess their values implications, stating that values must also be considered as a critical component in the design process (Knobel & Bowker, 2011). Values must be considered very early in the design process and as a part of the design requirements (Flanagan, Howe & Nissenbaum, 2005; Van den Hoven, 2013). Designers such as scientists and engineers must expand the set of criteria they normally use to evaluate systems to include social as well as technical values (Nissenbaum, 2001). Key to a VID approach is that technical constraints should be treated with the same level of importance as ethical issues (Nissenbaum, 2017). Such an approach validates the sociotechnical nature of technological design and realistically accounts for all types of constraints while attempting to avoid potential negative future-use impacts of a technology.

The perspective that both classes of values be treated equally as part of the design requirements suggests that VID scholars are aware that designers may resist attempts to consider nontechnical values during the design process. They are trained to think of the design goal as the creation of a physical (i.e., technical) object and that thinking about social issues takes time and attention away from the primary objective (Dias & Baptisa, 2020). Although there appears to be no uniform method that indicates what it means to use a VID approach, there is consistency among VID scholars that value-aware design should be pragmatic in orientation. Katie Shilton (2010; 2013; 2018a) argues that value considerations will become less burdensome if they are better streamlined within design practices. She encourages the use of *values levers*, which are

intentional, strategic ways to include values in discussions among members of design teams (Shilton; 2013; Shilton, 2018b). Shilton (2013) and others (Manders-Huits & Zimmer, 2012; van Wynsberghe & Robbins, 2014; Shilton & Anderson, 2017) also encourage taking a more explicit approach when incorporating values advocates in design teams. The purpose of these individuals is to advocate for ethics and values throughout the design process and to serve in an expert capacity by which they translate values for technical work (Shilton; 2018b).

Additionally, the VSD approach accounts for values in the design of technology, but does so in a more systematic and comprehensive manner when compared to VID. VSD emerged from the fields of information systems design and human-computer interaction and provides a framework with which to include values considerations in the design process (Borning & Muller, 2012; Friedman, Kahn & Borning, 2013). This framework features a three-prong iterative approach composed of conceptual, empirical, and technical approaches (Cummings, 2006; Manders-Huits & Van den Hoven, 2009; Friedman, Kahn & Borning, 2013). The conceptual stage is reflective and focuses on how values are either supported or diminished during the system design process. The empirical stage uses quantitative and qualitative methods to evaluate trade-offs between technical and social values in the design. Last is the technical stage, which focuses on the existing technical properties and mechanisms of the system and considers how they can be used or altered to better support social values.

This dissertation project is informed by both VID and VSD approaches. It draws on VID in the sense that values are a part of a socially constructed design process and that interventions need to happen early in the process. This project also aligns with VSD by implementing a conceptual approach to ground its initial assessment of the values of biomedical engineering laboratories as a sociotechnical system. Two important analytical activities take place in the conceptual stage that impact the overall assessment and evaluation of a system and its values

implications. The first is the identification of direct and indirect stakeholders associated with a technological design project and their values (Borning & Muller, 2012; Milchram, et al., 2018). Similar to steps one and two of the STINs model, part of this stage is the determination of who has a vested interest in the project.

The second analytical activity at the conceptual stage is the discernment of which values are implicated as a part of the design. The use of a particular values heuristic is advocated by some VSD scholars (Figure 8) (Cummings, 2006; Friedman, et al., 2013). However, proponents of the heuristic technique are quick to assert that this tool should not be thought of as fixed nor exhaustive. The values presented in the heuristic are said to have ethical import, which is often implicated in the design of a technological system (Friedman & Kahn, 2003; Friedman, Kahn & Borning, 2006).

VSD Values (with Ethical Import) Heuristic		
Human welfare	Universal usability	Accountability
Ownership and property	Trust	Courtesy
Privacy	Autonomy	Identity
Freedom from bias	Informed consent	Calmness
Environmental sustainability		

Figure 8
(Friedman, Kahn & Borning (2013))

The assertion that the heuristic presents "values of ethical import" appears similar in meaning when compared to Manders-Huits' (2011) definition of "values of moral import." Both descriptors refer to values that are associated with right and wrong behaviors and actions. However, while it is likely more of a conceptual slip between the use of "morality" and "ethics," the latter deserves more critical attention. One of issues of the VSD values heuristic is that it does not provide a standardized context in which to consider these values (Le Dantec, Poole, & Wyche, 2009; Borning & Muller, 2012). VSD does not explicitly commit to a particular ethical

theory, and without it, implicated values could be seen as more about stakeholder preferences than values with true moral importance (Manders-Huits, 2011; Jacobs & Huldtgren, 2018). Reference to ethical theories grounds a values approach by providing a source of justification and argumentation for morals claims. Such a reference point also helps designers make principled judgments and legitimizes the creation of certain trade-offs during the design process (Jacobs & Huldtgren, 2018).

2.2.4 Ethical Theories and Design Considerations

Ethical frameworks are based on the standards of right and wrong governing what humans should do in terms of rights, obligations, benefits to society, fairness, or specific virtues (Shilton, 2018b). Such frameworks are based on ethical theories that are grounded in particular moral principles. Some values and design scholars (Swierstra & Rip, 2007; Manders-Huits, 2011; Jonas, 2014; Jacobs & Huldtgren, 2018) argue that designers of technology would benefit from more explicit engagement with ethical theories throughout the design process. In support of this position, this project explicitly addresses ethical justifications as part of the values interventions proposed in Chapter 8 of this dissertation.

Five normative ethical approaches are particularly useful in a discussion about the values and design of sociotechnical systems. The approaches presented here are deontological ethics, virtue ethics, consequentialist ethics, ethics of care, and theories of justice.

Deontological ethics is a moral philosophy, where the morality of an action is based on whether that action itself is right or wrong based on a series of rules rather than on the consequences of that action (Waller, 2013). This approach, from a Kantian perspective, argues that to act in a morally right way means that an individual must act from a place of duty (Kant, 1785), that an action can only be good if the principle that drives it is based in the duty to uphold a moral law. Central to Kant's view of moral law is that individuals do not act in a manner that

treats others as the mere means to achieve a particular outcome (Guyer, 2011).

Another ethical theory is that of virtue ethics, which emphasizes virtues, or moral character, in contrast to (but not in exclusion of) duties or rules (Kawall, 2009). Virtues enable a person to perform their human function well and pertain to emotion and desire rather than the mind (Ameriks & Clarke, 2000). Virtues may be rooted in a universal human nature or in culture, but they are well-entrenched within a person (Hursthouse, 1999), such as virtues relating to having a sense of honesty and a disposition for performing honest actions including choices, attitudes, and expectations. The path forward likely depends on one's moral character as it relates to their virtues. Actions founded in such moral virtues are indicative of ethical action within the tradition of virtue ethics.

The notion of consequentialist ethics is based on the foundation that what constitutes a morally right act is one that produces a positive outcome. The moral worth of an action is determined by its consequence and not by whether it follows a set of laws or rules (Rachels & Rachels, 2015). Utilitarianism is a classic consequentialist theory (Bentham, 1789; Mill, 1861); it argues that an act is morally right only if it maximizes the happiness and wellbeing of affected individuals. The focus is on the consequences only versus the circumstances of the intrinsic nature of the act or of any choice that happens before the act. Ethical actions are those that do not decrease the happiness and wellbeing of others. The guiding principles of utilitarian thinking can be summarized in the adage "what is best for most is best for all." Utilitarianism serves as the dominant social way that people in the United States believe something is "intuitively" ethical (Baron, 2006; Bago & De Neys, 2019).

Another type of normative ethical theory to consider here is that of the ethics of care. One of the newer bodies of ethical thought, first presented by Carol Gilligan (1982), this theory developed within spheres of feminist thinking. Moral actions are said to center on interpersonal

relationships based on the assumptions that people have varying degrees of dependence and interdependence on one another and that individuals affected by the consequences of one's choices deserve consideration in proportion to their vulnerability (Schuchter & Heller, 2018). At the core of this theory is the virtue of care, which comprises the four ethical elements of attentiveness, responsibility, competence, and responsiveness (Tronto, Cudd & Andreasen, 2005). The ethics of care focus on the role of emotion in action, which is said to be typically ignored or denigrated in traditional moral theories because of its association with women and femininity (Bartky, 1990). Care is often devalued as an ethical action within theories because of its gendered association. To combat notions of care as an inherently feminine quality, ethics of care scholars emphasize natural care (in general and not associated with gender) over that of reason and logic, which are considered subservient (Tong, 1995; 2013).

Lastly, and related in some extent to virtue ethics and to ethics of care, are theories of justice in the Rawlsian tradition (Rawls, 1971). One of the central tenets to the theory of justice is the assertion that no one should be unfairly disadvantaged based purely on their membership in a particular group (e.g., race, gender, sexual orientation). Justice in the Rawls' sense reflects a social justice imperative standing against discrimination, targeting particular groups of people for negative treatment, and denying groups of people access to resources. Moral actions are those that do not infringe on the rights and liberties of others by not worsening one's quality of life or by exacerbating social or economic inequalities. Central to this approach are the principles of justice that serve and guide the conduct of various parties (Hume, 1739). Collective endeavors may be beneficial insofar as they promote the values of justice and fairness.

Researchers who study values and laboratory design practices may use ethical theories to ground their approach and justify their moral arguments. However, as discussed in Section 2.1, laboratory groups participate in a number of activities that require performing certain actions to

move forward with a research agenda. The reality of how work is performed throughout the design process may or may not reflect an intentional adherence to normative ethical principles and values. People often implicitly draw on various ethical principles (e.g., honesty, integrity, fairness) without being aware of it while performing their work. Many of the ethical actions made by individual laboratory members may better align with principles that are more implicit in their acceptance among a particular group. Researchers often face conflicting values imperatives when making decisions. For instance, the National Academy of Sciences Code of Conduct expects scientists to value honesty, fairness, collegiality, and openness (NAS, 2019). However, researchers may desire to make a name for themselves within their field, which could stand in contrast to the value of collegiality.

2.2.5 Responsibility, Transparency, and Ethical Technologies

Technological assessment perspectives often focus on the outcome or the consequences of using a particular technology. The desire to make changes to a technology often comes only when it is used regularly, and more information is known about its impacts. Nevertheless, the challenge with this approach is that designers of technology rarely have enough power to go back and make these changes once society becomes accustomed to using the technology. Proponents of socially conscious technological design approaches (i.e., responsible research and innovation, or RRI) should think about the designers themselves and their practices. Advocating for responsible design practices will ultimately result in more ethically responsible technologies.

One initiative established in the early 1990s studied the potential social implications suggested by mapping and sequencing the human genome (Bulger, Bobby & Fineberg, 1995). This initiative, known as the Ethical, Legal, and Social Implications (ELSI) program, ran in parallel to the Human Genome Project and received federal funds to study the consequences of this research. Some potential issues were those related to maintaining privacy of genetic

information, integrating new genetic technologies, and ensuring the subject of informed consent (NLM & NIH, 2020). The ELSI program has since been adopted by researchers working in other areas of biomedical technology development, such as nanotechnologies (Bjornstad & Wolfe, 2011), neuro-prosthetics (Berger, et al., 2013), and synthetic biology (Trump, et al., 2020). The benefit of an ELSI approach is that it provides a way to think about the broad social, economic, political, and environmental impacts of scientific research and development (Berger, et al., 2013). However, the approach has also been criticized for not responding sufficiently to public and societal issues (Genus & Stirling, 2018).

Some STS scholars (Stilgoes & Guston, 2017) suggest we are living in a time of post-ELSI science where merely the identification of negative social impacts from the use of a technology is not enough. Proponents of RRI approaches to science and technology argue that research and development practices should make the solving of societal challenges the primary focus (Owen, Macnaghten & Stilgoe, 2012; von Schmoberg, 2013; Smallman, 2018). RRI first appeared in the United States after the implementation of the National Nanotechnology Initiative[6] by the federal government in 2001 (Brey, 2012). RRI scholars called for researchers to use nanotechnologies to improve the environment and to focus on using technologies to address societal concerns. What makes RRI approaches different from others is the emphasis on technologies having the *right* impacts and accounting for this earlier in the design process (Owen, Macnaghten & Stilgoe, 2012). Whereas earlier technological assessment frameworks were deemed too reactive to negative social impacts after they occurred, RRI argues that technological development is a process, and one needs to look at the actions of those who make

[6] This federal program focuses on the science, engineering, and technology research and development for nanoscale projects. According to its website, it serves as the central point of communication, cooperation, and collaboration of all federal agencies engaged in nanotechnology research (www.nano.gov).

decisions before a technology is deployed.

Scholars who advocate for the development of socially responsible technologies argue that it is important to think about ethical considerations early in the design process when it is easier to make changes (Van den Hoven, 2013; Van der Burg & Swierstra, 2013). However, this approach comes with its own limitations, in that designers of technologies have the most power to make changes early in the process, but they also lack, at that point, the information needed to make those changes (Van den Hoven, Vermaas & Poel, 2015). Collingridge (1980) refers to this as the *double-bind problem.* The first issue is an *information problem,* where developers and researchers cannot easily predict the impacts of their technologies until they are extensively developed and used. The second issue is a *power problem,* where having control or the ability to change a technology is difficult once it becomes entrenched in society (Collingridge, 1980; Eden, Jirotka & Stahl, 2013).

The double-bind problem reaches to the heart of how technological evaluations focused on the ethics of technology always seem "too early" or "too late" in the design process (Kundina & Verbee, 2019). However, most technology assessment and evaluation frameworks continue to appraise technologies only after they are deployed rather than on actions taken during the entire design process. ELSI and RRI approaches reflect a consequentialist ethical position, which argues that moral actions are those that produce positive outcomes (Benthan, 1789; Mills, 1861). What makes for a responsible innovation is the way its use results in the protection or improvement of a person's wellbeing (Manders-Huit & Van den Hoven, 2009. This is a value that can only be assessed after a particular technology is used.

Some proponents of RRI approaches do believe, however, that *responsibility* should be about the designers behaving as responsible actors engaged in responsible actions (Verbeek, 2008; van den Hoven, 2013). In this context, responsibility is defined as having a *duty* to deal

with something or having control over someone, either as a human being living in the world or when serving in a particular role (Chandler, 2017). The question of who or what has the duty of responsibility throughout the design and development of novel technologies involves multiple stakeholders, each with distinct yet interconnected goals and aims.

The multiple stakeholders of a technological design project share what Luciano Floridi (2016) refers to as distributed moral responsibility to act in ethical ways throughout the design process. Responsibility cannot be allocated to one central actor, as everyone works together in an effort to achieve a collective end (Helberger, Pierson & Poell, 2018). For example, the human genome project was a huge scientific project requiring scientists, governments, private companies, and others to work together to map the entire genome.

The value of responsibility also relates to the value of transparency, especially if, during the design process, a stakeholder is found to be taking action in ethical violation of their duty or role. Calls for greater transparency into the technological design process make it easier to see what actions are performed when a system is being designed (Iqbbal, et al., 2016). For example, scholars who address the reproducibility crisis in science (Jansy, et al., 2011; Couchman, 2014; OSC, 2015; Vicente-Saez, 2018) argue for greater transparency in research practices. The behaviors and actions of biomedical engineers, for instance, are largely unknown to those who are outside the laboratory. The decisions they make while engaged in the technological design process ultimately result in the *black-boxing* of a technological system where the contents of that system become hidden from the user or are made mysterious (Bijker, Hughes & Pinch, 1987). Black-boxing also obscures the power relations involved in creating a system (Callon, 1984; Law, 1992), how values are contested, and whose values eventually win out. There is a need for greater transparency into the technological design process of biomedical technologies to hold stakeholders accountable for acting and behaving responsibility.

Ethics and values expectations based on professional roles and responsibilities are just one type of institutional influence associated with laboratory work practices. The next section introduces additional institutions that shape biomedical research practices and the design of novel technologies.

2.3 Institutions of Science and Technology

The second half of the 20th century witnessed important changes in the relationships among government, university, and industry research and development (R&D) stakeholders. This relationship changed in response to World War II and the concern that other countries would outpace U.S. intellectual and commercial advances (Stokes, 1997). Vannevar Bush, then the director of the Office of Scientific Research and Development (OSRD),[7] argued in his now-classic report, *Science, the Endless Frontier* (1945), that there is a difference between basic and applied research. Bush argued that, if basic research is "appropriately insulated" from premature considerations of use, the innovative discoveries it finds will be better able to meet the range of society's needs. Universities were suggested as the best places to perform basic scientific research, since they face the least pressure to produce tangible results (Kumar, 2010). As a result, government funding for university-based research increased dramatically after the end of WWII (Pavitt, 2013).

Ideological tensions among R&D stakeholders increased over the next few decades, and some university researchers resisted increased government intervention into academic spaces. Researchers argued that such spaces are the bastions of knowledge-based public goods (Giroux, 2002), but this stood in contrast to the rising neoliberalism of the 1960s and 1970s in the United States (Etzkowttz, 1994a). Neoliberal policies took a turn toward greater deregulation and

[7] The OSRD dissolved in 1947 but was soon followed by the establishment of the National Science Foundation in 1950 (Zachary, 2018).

privatization, while more political and economic practices proposed that human wellbeing is best advanced by "liberating individual entrepreneurial freedoms and skills" within institutional frameworks (Harvey, 2007). Stakeholders soon wanted to see more return on investment for university research sponsored by federal funds and argued for government ownership of resultant innovations via patents (Eisenberg, 1996; Johnston & Wasunna, 2007). The Bayh-Dole Act (BDA) was enacted in 1980 and allowed both nonprofit organizations (e.g., public universities) and small businesses to retain ownership of inventions created under contract with the government (Cornell, 2019). The BDA did help to settle some of these tensions, but it also institutionalized neoliberal standards of private ownership and entrepreneurial values in scientific academic spaces.

2.3.1 Neoliberalization of University Innovation: Technology Transfer and Resistance

Etzkowitz and Leydesdorff (1995) propose the triple helix model to conceptualize the multiple reciprocal linkages that occur among these three institutional actors throughout the R&D process. The helix represents an institutional tool and dynamic mechanism that drives regional innovation through interactions of related and relevant actors in various societal circumstances (Etzkowitz & Zhou, 2017). Central to this theory is the recognition that, by the late 20th century, the sociopolitical landscape was now supported by knowledge-based forms of production and economic development (Etzkowitz, 1994b). What once constituted the boundaries among the three sectors of industry, university, and government had changed. The government now has more involvement in university spaces (e.g., through funding and grants), and industry partners (i.e., commercial entities) play key roles in this evolving model of innovation. Universities have become economic players through patents and start-up companies, which changes how science happens within academia. Cultures of innovation are now the institutional context in which laboratories are situated and shape their practices (Munshaw, et al.,

2018). The values associated with this context trickle down from the institutional level to the department level and ultimately to the workgroup level, and impact the attitudes of laboratory researchers who engage in university-based R&D projects (Kleinman, 1998).

Although not all researchers purposefully set out to receive patents, there is an increased awareness in these communities of the values associated with innovation (Pattyn, 2006; Sanberg, et al., 2014). Often, these values are characteristic of what is used to determine patent eligibility, such as novelty, nonobviousness, and utility (Moreno & Joly, 2015). One cause for this increased awareness about patents among scientific researchers is the implementation of technology transfer offices (TTOs) across university campuses in the United States. The first U.S. TTOs were initially inspired by the after-effects of the BDA and were implemented in the mid- to late 1990s (Jones, 2005). The primary purpose of TTOs is to help university-based researchers file for patents for their innovations and to facilitate potential connections with industry partners.

However, some faculty may still resist working with TTOs, avoiding seeking patents in general unless doing so is factored into their performance evaluations and tenure cases (Sanberg, et al., 2014). Some faculty may also resist giving performance credit to those who seek patents and view it as a misalignment between the democratic ideals associated with normative academic values (e.g., the production of public goods and free knowledge) and those associated with neoliberal economic goals and for-profit commercial values. Such a perspective may lead to continued feelings of resistance toward the presence of TTOs on university campuses (Sampat & Nelson, 2002; O'Kane, et al., 2015); however, such resistance also likely varies by disciplinary culture.

The values of the open science movement also motivate resistance to neoliberal goals in scientific spaces. The movement seeks to make scientific research—including publications, data, physical samples, and software—freely accessible to all levels and members of society (Woelfe,

Olliaro & Todd, 2011). The values of this movement are also reflected in the growing number of government funding agencies (e.g., National Science Foundation, or NSF, and the NIH) that require researchers to provide open access to their data (Pasquetto, et al., 2016). Part of the motivation behind these open-access initiatives is to advance scientific research and innovation, because, as suggested by Christine Borgman, et al., (2012), "Datasets have little scientific value…if the associated hardware, software, protocols, and other technologies are proprietary" (pg. 211). Additionally, open-science initiatives draw attention to issues of transparency and reproducibility in research practices; they make it easier for others to see what actions are performed during the research process (Vicente-Saez, 2018) and to what extent consistent results can be observed and repeated (Jasny, et al., 2011).

2.3.2 Biomedical Research and Translational Medicine

The largest government funder of biomedical and public health research in the United States is the National Institutes of Health (NIH). The NIH invests more than $37 billion annually into medical research (Philippidis, 2019; NIH, 2020) and has made a major push in the past 15–20 years to support and fund biomedical research focused on *translational medicine*. The concept was originally introduced in the pharmaceutical sciences but has rapidly been adopted for use in all areas of biomedical research (Gordon, et al., 2014). Translational medicine is defined as:

> [A] discipline within biomedical and public health research that aims to improve the health of individuals and the community by "translating" findings into diagnostic tools, medicines, procedures…[it is] an effort to carry scientific knowledge "from bench to bedside"; translational medicine builds on basic research advances…and uses them to develop new therapies or medical procedures. (Wehling, 2015)

The NIH has been especially effective at communicating a normative characterization of the stages of research and development associated with translational medicine. In early 2000, the NIH established a task force to develop a translational roadmap, which situates research and development activities unique to biomedical researchers (Drolet & Lorenzi, 2011). In 2003, the

NIH presented a roadmap suggesting that the successful translation of research findings into clinical applications follows a five-stage continuum of activities (Figure 9) (Zerhouni, 2003). The intent of the translational roadmap is to bring faster, less expensive, and more effective translation of the basic research happening in laboratories to clinical applications that have benefits for patients (Moreno & Joly, 2015).

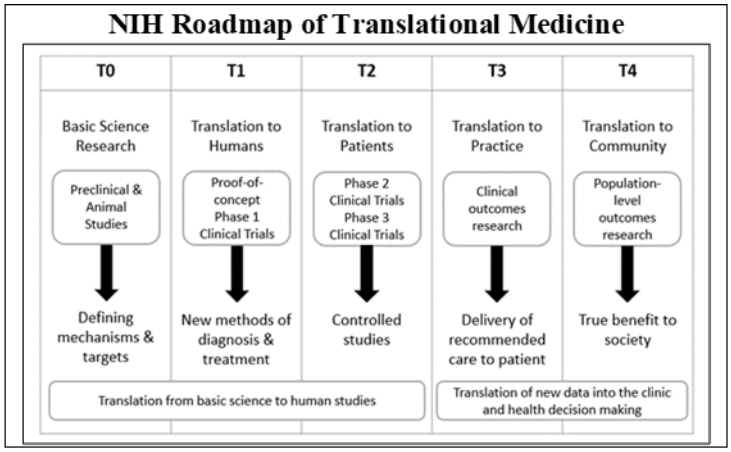


Figure 9
(Adapted from Liverman, et al., (2013))

Basic research activities are characterized as those that happen *upstream* (e.g., stage T0) in the development process, which differ from clinical and patient outcomes that happen *downstream* (e.g., stages T3 and T4) (Kumar, 2010; Vienot, 2019). As a project moves from the T0 stage toward the T1 stage, more attention is placed on moving the technology to the stage where it is tested on human subjects. In vivo testing continues until a viable *proof of concept* is proven (Bensaude-Vincent, 2013). Technologies that indicate the most promise, via accurate preclinical testing data, must demonstrate at the T1 stage that they are effective and achieve the targeted aims (e.g., effectiveness, safety). Once this happens, human subjects are introduced into the process via phase 1 clinical trials.

Technologies that move to the T2 stage go through at least two more stages of clinical trials to demonstrate their efficacy and safety for humans. Biomedical technologies, for instance,

must prove their use has more benefits than harms to humans. Biomedical technologies that advance onto stage T3 are then available for application within clinical settings and can be used to treat patients. This would likely result in the generation of positive clinical data at stage T3, which could then be used to measure positive impacts to the community in stage T4 of the process. Very few novel biomedical technologies, however, successfully transition from the primary stages of translation (T0-T1) to the secondary stages (T3-T4), and for those that do, the process takes an average of 15–20 years (Ioannidis, Kim & Trounson, 2018).

Although the reasons for this delay in development continue to be a matter of much debate and discussion (Marion, Dunlap & Friar, 2015; Wehling, 2015; Ioannidis, Kim & Trounson, 2018; Anderson, et al., 2019; Summers-Trio, et al., 2019; Strand, 2020), the exact causes are not fully understood. One of the prominent beliefs is that a disconnect happens between upstream academic researchers and downstream industry stakeholders that hinders effective translation. Some of this disconnect is due to challenges associated with *scaling up* a proof of concept to something that can be produced on a mass commercial scale further downstream (Gardner & Webster, 2016; de Lorenzo & Couto, 2019). Others argue that breakdowns in the process happen further upstream and well before scaling up enters the conversation. Ioannidis, Kim, and Trounson (2018) argue that delays in translation are often due to suboptimal research practices, including faulty study design, poorly characterized materials, and a lack of understanding of the relevant biology.

There is a need to closely examine how biomedical researchers actually traverse the translational landscape in their everyday laboratory practices. This is especially important for research groups like biomedical engineers, whose disciplinary identities are founded on the principles and values associated with innovation and novelty.

2.4 Biomedical Engineering and Technological Assessment

Understanding the history of biomedical engineering as a discipline provides important insight into the contemporary norms and values found within the field. The field of biomedical engineering can be traced to the late 19th century when engineers developed instrumentation (e.g., imaging, measuring) that impacted medicine and biology. The emphasis on using electronic devices in clinical settings lasted well into the 20th century, and by the 1920s and 1930s, researchers began to deliver more concepts and techniques from physics biomedical research (Nebeker, 2002). The first university to establish a program in "biological engineering" was the Massachusetts Institute of Technology in 1937, followed by UCLA's program in biotechnology and "human factors research" in the late 1940s (Bud, 1994; Owens, 2004). Part of the reason for the increase in biomedical technological innovation heading into the 1950s was the government's push in the post-WWII era to financially and ideologically support these projects.[8]

The first biomedical engineering programs were established in the late 1960s.[9] The U.S. government also implemented (and further institutionalized) NIH programs targeting the infusion of engineering into areas of biomedical research (Hendee, et al., 2002).[10,11] The 1980s saw the introduction of recombinant DNA technologies, and the greatest changes to the discipline happened throughout the 1990s, starting with the launch of the Human Genome Project (HGP) in 1990.[12] The NIH was the primary U.S. funder involved, but the project itself required the collaborative efforts of dozens of governments, academics, and industry stakeholders. This

[8] NIH appropriations increased from $32 million to $213 million by the end of the 1950s (NIH, 2020b).
[9] Programs were established at universities such as Case Western, John Hopkins, Duke, and the University of Virginia (Bud, 1994).
[10] Biomedical engineering programs are accredited by the Accreditation Board for Engineering and Technology, and as of 2019, there were a total of 92 ABET accredited stand-alone degree-granting biomedical engineering programs in the U.S.
[11] The number of biomedical engineering programs in the U.S. rapidly increased in the early 1970s, and by 1974 there were a total of 121 programs; of which, 7 granted undergraduate degrees (Hart, 2015)
[12] It ultimately cost $3 billion dollars to complete the HGP (Collins, Morgan & Patrinos, 2003).

dream of the HGP is based on the belief that understanding the genome will lead to the mapping of all cells, tissues, and organ functions of a human body to their genetic programs (Reardon, 2017). The excitement surrounding the HGP led to a significant influx in both public and private funding into biomedical engineering programs with the hope that, as more discoveries were made, more employment opportunities would present themselves. Additional professional organizations were founded throughout the 1990s, such as the American Institute for Medical and Biological Engineering, with the explicit purpose of addressing issues relevant to the medical and biological sciences (AIMBE, 2020).

2.4.1 Bringing Biology and Engineering Together

The biomedical technological and informational changes of the 1990s brought an unprecedented level of attention to the role of biology within biomedical engineering. While the past six decades had witnessed the merging of electrical systems and physics with healthcare technologies, the biology revolution within the field began in the 1990s. Professor Robert Nerem[13] declared in a 1997 article that "biology will define scientific progress in the 21st century" and that "biology has truly come of age, achieving an importance equal to that of physics and chemistry." He also predicted a surge in the development of new bio-based industries, because "biology has become too important to be left to the biologists." Such declarations are indicative of Nerem's values. Why should biological authority no longer be the domain of biologists? And if biologists no longer serve in that capacity, who does, and why?

By the end of the 1990s and into the 2000s, universities wanted to see more biology

[13] Nerem joined Georgia Tech in 1987, and also served as associate Director of the NSF Science and Technology Center for the Emergent Behavior of Integrated Cellular Systems, Director of the Georgia Tech/Emory Center (GTEC) for Regenerative Medicine, and until 2009 was the Founding Director of the Parker H. Petit Institute for Bioengineering and Bioscience, an interdisciplinary organization for biochemistry, bioengineering, and biology. For more information see: https://ibb.gatech.edu/

integrated into the engineering curriculum. The purpose of biomedical engineering is seen as a way to bring biology and engineering together to better address medical issues and challenges. The attention now given to biology is an attempt to define engineering in relation to biology; it is an approach reminiscent of how electricity and physics were used throughout the 20th century. Attempts to merge disciplines are complicated processes because of the tensions that arise from blending their cultural differences. Every discipline has its own history and set of attributes, which makes true interdisciplinarity quite difficult to reach.

As an example, one can consider the differences between biology and engineering based on Kirshnan's (2009) list of six disciplinary characteristics. Their objects of study differ, as biologists study humans, plants, animals, and their environments, while engineers study technology and science focused on the design of engines, machines, and structures. Biology relies on a body of accumulated knowledge from the sciences, and engineers use a body of knowledge based on building and design. Biologists are said to study phenomena to gain more knowledge, whereas engineers are trained to be problem-solvers. Each discipline uses specific terminology, such as macrophage, lipid, and assay for biologists and stress-strain, torque, and exothermic for engineers. Biologists are also more likely to engage in hypothesis-driven research, and engineers more commonly undertake data-driven research. Lastly, each discipline has its own academic department and its own professional associations. These disciplines each have cultural characteristics based on their customs, practices, transmitted knowledge, beliefs, morals, and the meanings they share (Baily, 1992; Becher, 1994). Attempts to combine disciplines invariably result in cultural tensions; however, such tensions may act out differently depending on how they are brought together.

Disciplines may be combined to work on a shared problem; this is defined as multidisciplinary. When something is multidisciplinary it suggests that the disciplines

themselves remain as they are, but they share information with each other that is integrated into the knowledge base of each discipline (Tolk, 2017). Multiple disciplines may also come together in a way that ultimately transcends their traditional boundaries. This type of transdisciplinarity extends beyond the creation of a common structure for research and opens new ways of knowing and doing research (Fawcett, 2013). This research is driven by specific and compelling problems with a focus on deep integration across disciplines (Sharp, Jacks, & Hockfield, 2016).

Biomedical engineering most comfortably reflects the characteristics often associated with interdisciplinarity. This approach combines two or more disciplines to work on solving problems by sharing data, information, and functions, which likely create new domains when research areas and methods are intertwined (Stock & Burton, 2011). The process is reciprocal and integrative and works to synthesize diverse disciplinary perspectives, which may lead to a new disciplinary concentration or to an entirely new discipline. Interdisciplinarity combines different conceptual frameworks, which are believed to lead to innovation and scientific progress (Calvert, 2010; Rowbottom, 2011). Emphasis on interdisciplinary collaboration has increased within engineering disciplines over the past two decades (Andersen, 2016).

The existence of different disciplinary epistemic standards and values, however, can pose great challenges for interdisciplinary collaborations and ideological integration (Green, 2017). The field of biomedical engineering brings together two distinctly different disciplinary domains: biology and engineering. Are the norms and values expected of biologists *qua* scientists compatible with those expected of engineers? The Mertonian norms associated with scientific practice suggest a normative view of scientists as objective, rational, and neutral. However, the extent to which these norms and values are truly enacted in laboratories is a key question of this dissertation, and this provides insight into the normative values expected of biologists. Are the norms and values expected of engineers compatible with those expected of biologists?

One of the core indicative elements of an engineering education is training in the *principles of design.* In the classic introductory engineering textbook, *Exploring Engineering: An Introduction to Engineering and Design,* the authors emphasize the importance of using systematic methods to approach design. They state that engineers should be trained early in their careers to use the "need-know-how-solve" method to address problems (Kosky, et al., 2013). They and others (Robison, 2016) assert that this method provides a systematic approach to design, which accomplishes two goals. First, it eliminates personal bias from the process, and second, it maximizes the amount of thinking and information gathering up front before committing to a final design. This classic engineering approach begins with a design problem that engineers then probe with questions as they seek a solution. This method is, to some extent, at odds with the values of biologists, if one accepts knowledge exploration as *the* goal of this group of researchers. For instance, if a biologist seeks to prove or disprove a hypothesis when conducting an experiment, the goal is achieved by reaching this answer regardless of what it is, not by "solving" a particular problem.

This standard engineering design method also implies a linear approach to problem-solving that is rarely so neat when performed in practice. STS scholar Joan Fujimura (1987) suggests that to construct truly "do-able" problems, three levels of work organization must align adequately. The first level is the experiment level, in which a set of tasks are carried out in the laboratory. The second is the laboratory level, in which many types of experiments and other tasks take place. The third is the larger social world, in which experiments and laboratories are situated. Fujimura (1987) argues that alignment is achieved when which researchers consider, collect, coordinate, and integrate tasks between these levels of organization. This requires a type of tinkering (Knorr-Cetina, 1979), of moving back and forth between the levels until all parts are collected and made to fit together. Communication and coordination are needed when multiple

stakeholders are involved and to achieve particular solutions to the problem (Abma, et al., 2017). The principle of design approach also instills a way of thinking among engineers that instructs them to value problem-solving as a part of their professional identities. Again, this is not the same for those who identify themselves as basic science researchers (i.e., biologists engaged in knowledge exploration).

Engineers are also trained to leverage principles found in the natural world to build systems, an approach valued by those engaged in applied scientific activities. They think about elements within the system and how to design solutions for the problems they encounter (Gershwin, 2018). For example, an electrical engineer who builds a circuit board for a device needs to have some understanding of physics to make that system work. They are using a natural element within a newly constructed system. The manipulation of the natural world comes with a certain level of professional responsibility (Tokar, 2001) and is addressed within professional societies such as the National Society of Professional Engineers (NSPE). The NSPE provides a Code of Ethics for Engineers,[14] which emphasizes the importance of acting responsibly and protecting the safety, health, and welfare of the public (NSPE, 2019). Although codes may not explicitly reference a governing mechanism to enforce certain actions and behaviors, they do impose a set of implicit moral obligations for people serving in professional roles *as* they build systems.

[14] The NSPE first approved the Canons of Ethics for Engineers in 1946 which lists 6 fundamental canons engineers should fulfill in their professional duties. These canons remain the same in NSPEs most recent version of the now entitled Codes of Ethics for Engineers.

CHAPTER 3: METHODOLOGY

This chapter presents detailed information about how data were collected and analyzed to answer the research questions presented in Chapter 1. The results of this project are based on the findings of more than 300 hours of observations, 44 individual interviews, and the analysis of hundreds of pages of documents. The research and development activities of 15 university-based biomedical engineering laboratories at five R1 public institutions in the United States are represented.

This chapter is divided into four primary sections. The first section describes the rationale behind the use of observations, interviews, and document analysis as the methods to conduct this study. The second section provides a description of how data about biomedical engineers were collected using embedded observations, visiting laboratory field sites, conducting individual interviews, and analyzing documents. This section includes a presentation that divides collected data by the type of biomedical engineering laboratory, cell-based and device-based, included in this study. The third section describes how a modified grounded theory approach was used to code and analyze the data. This chapter concludes with a brief discussion of the potential limitations when using this approach.

3.1 Rationale of Methodology

David Foster Wallace delivered a now-famous commencement speech at the 2005 graduation ceremony of students at Kenyon College. He opened his speech with this story:

> There are these two young fish swimming along and they happen to meet an older fish swimming the other way, who nods at them and says, “Morning, boys. How’s the water?” And the two young fish swim on for a bit, and then eventually one of them looks over at the other and goes, “What the hell is water?”
>
> (Wallace, 2009)

Wallace explains that the point of this allegory is that the most obvious and important realities are often the ones that are the most difficult to see and talk about. I add to this that the fish do not

comprehend the reality of water because they are in it and long have been.

In this dissertation project, I take the position that biomedical engineers do not see elements of their values system, because, as they are enculturated into their discipline, they presuppose their values system. They affirm certain facets of their laboratory work practices, which, in turn, limits their conscious awareness of how and where certain values enter into the design process. As a researcher trained in neither engineering nor the sciences, I enter biomedical engineering laboratories as a novice. My experiences in these environments enable me to serve as data collection instrument (Wa-Mbaleka, 2019), open to witnessing values in action from a unique perspective. As social scientist, using ethnographic methods provides access to laboratory working environments not usually made available. They help me develop the type of thick description that Clifford Geertz (1973) says will provide a comprehensive account of the field and the identification of social patterns within a particular context. Use of these methods provides firsthand experience to witness and record the feelings, perceptions, attitudes, and behaviors of biomedical engineers. They aid in making explicit those values that are typically enacted implicitly in these discipline-based work practices.

In this project, I observed biomedical engineers as they worked in laboratories and participated in professional conferences, and I conducted semi structured interviews with participants inside and outside of these environments. Using these methods was especially helpful when determining and describing the values dimensions of a particular sociotechnical system. Values dimensions are those composed of sources and attributes of the values themselves (Shilton, Koepfler & Fleischmann, 2013). For example, one source dimension is that of the *unit* in which values are generated and where values move along the spectrum of the individual (i.e., held by a person) and values of the collective (i.e., goals embedded in the sociotechnical context) (Nissenbaum, 2009; Shilton, Koepfler & Fleischman, 2014). The use of

observation works to reveal the values of the collective as they are performed within laboratory settings. However, to observe the values of individuals, interviews provide an opportunity to speak one-on-one with researchers. The interview process is used to discover what is important to the individual and to identify any potential areas of value conflicts between themselves and their work group or organization (Shilton, Koepfler & Fleischman, 2014). Interviews also allow participants the opportunity to have some control over how they present themselves, an option less feasible when engaged solely in observation.

3.1.1 Previous Laboratory Ethnographies and Studying Values

The methodological design of this dissertation project is informed by previous ethnographic studies of laboratory practice and adopts a constructivist view of scientific practices as shaped by social structures. The use of interviews in addition to observations enables a comparison between biomedical engineers' and researchers' normative values (i.e., values the engineers and researchers *should* have, as they have expressed in interviews) and their descriptive values (i.e., what values they *actually* have in practice). The use of observations provides a way to be physically next to researchers as they engage in their work practices. This provides an opportunity to see how activities are done firsthand and to tap into their frame of mind. Interviews provide the engineers and researchers the opportunity to reflect on these observations and to exercise some control over how they present themselves to the interviewers.

The combined use of these methods can help identify any misalignments between the normative values and descriptive values of a laboratory and its members. In Latour and Woolgar's (1979) anthropological study of the Salk Institute for Biological Studies, the researchers reflect on Latour's experience of having spent years embedded with and observing the everyday activities of scientists in the laboratory. This approach to the study of laboratory researchers gave Latour the vantage point to see how scientists engage in real work practices and

compare these practices to those assumed by Mertonian norms. What do scientists really think about as they conduct an experiment? What is important to them as they attempt to collect the data and write about the results of their projects? Latour and Woolgar used their firsthand observations and interviews to consider how the values and norms of researchers compared to Mertonian norms and concluded that "the explanatory power of [Merton's] norms falls well short of objective understanding both of science and the scientists who make it" (Latour & Woolgar, 1979, p. 190).

Cultural values associated with the stages of career progression were also identified by symbolic interactionist Sharon Traweek (1988) in her study of the social structures of high-energy physicists. In this study, she uses ethnographic observation to examine how laboratories are organized, how groups build and design detectors, and how leadership styles vary. Traweek found through her observations that tacit knowledge—the ideas and skills not explicitly articulated nor learned from formal or codified sources of knowledge—was essential to the knowledge-making progress in these laboratories (Traweek, 1988; Hau, Kim & Lee, 2016). Such knowledge is gained in collaboration with others as a part of their shared experiences and reflects the values and norms of the culture (Jeon, 2019). Laboratory group members often cannot articulate these norms and values, and Traweek was only able to capture them by observing the scientific laboratory practices.

Similarly, in an early work within the field, Knorr-Cetina (1981) observes the everyday laboratory activities of protein scientists and suggests there is a "contextual nature" in the way that researchers reason. Knorr-Cetina's position as an observer enabled her to identify the elements indicative of this context. One of her most critical findings is based on her observational participation in the laboratory. She argues that what a laboratory presents as its knowledge product is based on locally situated practices and the "occasioned" (i.e., artificial)

character of laboratory selections (Knorr-Cetina; 1979; 1981).

Contemporary values and design scholars, such as Batya Friedman (2017) and Katie Shilton (2011; 2013; 2018b), also use ethnographic methods as they study values and the design of sociotechnical systems. Friedman observed office employees throughout their workday to note their interaction with a screen that displayed the natural surroundings of the building. The screen reflected not only the nature images but also any people who happened to be in the areas being filmed. The use of observation led to critical values findings in her study related to privacy, trust, and security.

In a multiyear project with the Center for Embedded Networked Sensing (CENS), an engineering laboratory associated with UCLA, Shilton (2011; 2013) used ethnographic methods to examine the design practices of laboratory members responsible for building ubiquitous computer technologies. Shilton observed how engineers interact with one another about their system designs, and she identified how values compete as design priorities when used to rationalize design decisions. She also used interviews to discuss her observational findings with study participants. The overall findings of this ethnographic work led to her identification of when and where *values levers*[15] and *ethics advocates*[16] should be inserted into the actual work processes of a design team (Shilton, 2010; 2011; 2013; 2018b).

Comparative ethnography of two disciplines is also useful for characterizing the culture of each. In a later work by Karin Knorr-Cetina (1999), she takes this approach in her study of two different scientific laboratory cultures. She uses both observations and interviews to compare and contrast the norms and values of each scientific group as it is rooted in its own

[15] Shilton (2013) defines values levers as activities that open new conversations about social values and encourage consensus around those values as design criteria.
[16] Shilton (2010) defines an ethics advocate as someone who should be included as a member of design teams and whose primary task is to lobby for social and ethical concerns throughout the design process.

disciplinary culture (Kitchener, et al., 1993; Knorr-Cetina, 1999; Reinholz, et al., 2019). Through these observations and interviews, she finds that each group does not engage scientific methods in the same way. Additionally, she learned that they differ in how to define empiricism, how to relate to objects in the laboratory, and how to socially interact.

The methodology used in this dissertation is informed by the research design of these previous laboratory ethnographies. As with those before it, this project uses observations, interviews, and document analysis to examine the cultural contexts in which biomedical engineering laboratory practices take place. However, unlike previous studies, this project takes a comparative approach of laboratories located within the same discipline, but that design novel biomedical technologies at different stages of clinical development. The next section describes how data were collected for this project as well as what types of data were gathered.

3.2 Data Collection

The empirical data for this project were collected over the course of 18 months, stretching from November of 2017 to July of 2019. Ultimately, 300 hours of observation were logged based on time spent embedded in a cellular biomedical engineering laboratory, visiting additional laboratory field sites (primarily device-based), and attending conferences and lectures. A total of 44 laboratory group members were interviewed individually; they represent the design activities of 15 biomedical engineering laboratories at five publicly funded R1 institutions in the United States.

3.2.1 Identification of Laboratory Participants

Laboratories were targeted for recruitment based on having similar research agendas as determined by an examination of their university-supported group websites. Those who were contacted were chosen based on two primary criteria. The first criterion was the type of novel biomedical technology in development in a laboratory group, specifically, if the technology was

cell-based or device-based. For example, many biomedical engineering laboratories are designing technologies intended for use at the cellular level. These groups research how to build entirely *novel systems* using new materials, methods, and modes of treatment delivery (e.g., cellular-level drug delivery). Only a handful of technologies in this category have advanced as far as early-stage clinical testing in the development process. These laboratories were classified for inclusion as members of the cell-based group of biomedical engineers (also known as cellular biomedical engineers). Laboratories developing novel device-based technologies were also targeted for recruitment. This group is composed of biomedical engineers who design *novel applications* to work with devices that have already advanced through every stage of translational development. These laboratories were classified for inclusion as members of the device-based group of biomedical engineers (also known as biomedical device engineers).

The second criterion used to identify laboratories for recruitment was the stage of development of the technology itself—specifically, whether these technologies were considered to be in the preclinical stage of development, or whether significant parts of the technology were already in use in clinical settings. For example, many of the included biomedical device engineering groups work with technologies, such as MRI machines or prosthetics, for which the core component is already regularly used for clinical applications. These newly *optimized* or *enhanced* biomedical device technologies may or may not need to revisit earlier stages along the translational continuum. Biomedical device engineers represent a group of technological designers who work at the later stages of translation (e.g., stage T3), and when considered within the context of the Collingridge dilemma, this means they arguably should have the most information to change facets of the technology based on concerns about causing negative social impacts. Conversely, on the other end of the development spectrum, cellular biomedical engineers work at the earliest stages of translation (e.g., stage T0), where, conceivably, they have

the most power to make changes to potentially harmful technological systems.

Each group of biomedical engineers engages in laboratory work practices that correspond to very different stages along the translational pipeline. How researchers in a biomedical engineering laboratory should consider and respond to the potential for negative social impacts of the technologies they develop will differ because of their given relationship to translation. Proposed values interventions into the design practices of these laboratories should be inserted at different stages along the translational pipeline.

3.2.2 Recruitment Process and Participant Information

Initial laboratory recruitment efforts focused on finding a biomedical engineering laboratory (either cell-based or device-based) that would allow me the opportunity to embed myself within the group and observe their daily activities for a certain period of time. Multiple rounds of recruitment emails were sent to faculty laboratory leaders (the PIs) who were identified after an examination of their laboratory group websites. Each PI was sent a project information sheet (see Appendix A) approved by the institutional review board (IRB), which was used to gauge their potential interest in participation. Once a biomedical engineering laboratory PI agreed to provide me embedded access to their group, I spent approximately 250 hours, visiting one to two days a week over nine months, observing a variety of routine research practices in this particular cellular biomedical engineering laboratory. During this period, I also continued to reach out to additional laboratories in an effort to spend time observing their activities as well. Ultimately, an additional five laboratories, making for a total of six groups, agreed to participate in observations and site visits. Pseudonyms were assigned to each participating university.

The decision to continue reaching out to additional laboratories was based primarily on my curiosity about whether biomedical engineering laboratories work in the same way. Initially, this led me to contact laboratories that also designed cell-based technologies. However, after

visiting two more cellular biomedical engineering laboratories, and after logging many more hours of observation at my main laboratory site, I found participants hinting at differences between cell people and device people within the field (Figure 10).

Observed Field Sites

Institution	Lab Type	Specialization	Time
Purple University	Cell	Molecular Drugs & Cell Tracking*	250+ hours
	Cell	Genetic Engineering	6 hours
	Device	MRI & Nuclear Imaging	8 hours
Green University	Device	Upper-Limb Prosthetics	10 hours
Orange University	Cell	Molecular Drugs & Gene Therapy	2 hours
	Device	MRI & Ultrasound Imaging**	20 hours

Figure 10
*** Tango Laboratory**
**** Bravo Laboratory**

Admittedly, when I entered my first laboratory in late 2017, I did not appreciate the differences between biomedical engineering laboratories that design cell-based technologies and those that design device-based technologies. I also was unaware of the translational roadmap and how the research activities of biomedical engineering laboratories correspond to different stages along that roadmap. These initial data inputs, and the beginnings of the associated emergent findings, shaped the next stages of my data collection process.

The additional field sites I visited were all biomedical device engineering laboratories. These visits gave me the opportunity to observe approximately 35 more hours of laboratory activities, and they differed significantly from those witnessed in cellular biomedical engineering laboratories. One of the strengths of this dissertation project is that it compares the values of two groups of biomedical engineers, not only in relation to the type of technology they design, but also by the stage of development of those technologies. This comparative approach would not have been possible without these additional field-site visits.

The final results of this dissertation project represent the values associated with the

laboratory research activities of 15 biomedical engineering groups at five R1-level research institutions in four different geographical areas[17] in the United States (Figure 11). The figure indicates how many of the 15 labs work on cell-based technologies and device-based technologies, as well as the total number of laboratory members associated with the participating laboratories at each university. This figure also indicates the number of laboratory members interviewed at each institution.

Participating Laboratories				
Institution	**Cell Labs**	**Device Labs**	**People**	**Interviews**
Green University	2	2	42	9
Purple University	2	1	26	12
Orange University	1	2	28	9
Red University	2	1	20	9
Gray University	1	1	24	5
Totals	15		140	44

Figure 11

All of the laboratories represented in this study are located in departments of biomedical engineering and are a part of colleges of engineering. Each laboratory is led by a single faculty member (tenured or tenure-track) PI, does or does not have postdoctoral researchers, and has a number of advanced and junior-level doctoral students. The smallest laboratory group has four members, and the largest has 23 members.[18] The average biomedical device engineering laboratory has seven members: one PI, two postdocs, and four doctoral students. The average cellular biomedical engineering laboratory has 11 members: one PI, three postdocs, and seven doctoral students.

3.2.3 Observations, Interviews, and Document Analysis

This project implements a triangulation approach to its overall methodology of data

[17] The geographical areas represented are the Eastern, Midwestern, Southern, and Western regions.
[18] Size totals do not include undergraduates or master-level graduate students as they are often short-term group members and do not participate in group decision-making or the planning of design activities.

collection. This study includes the use of observations, interviews, and document analysis as ways in which to gather data on the same topic. The purpose of triangulation is not to validate data using multiple methods but to examine different dimensions of the same phenomenon (Jonsen & Jenh, 2009). This approach serves as an important foundation in the development of a comprehensive description and evaluation of a particular social setting.

Approximately two-thirds of my observation hours were logged while embedded in a cellular biomedical engineering laboratory. This lab focuses on the use of quantum dots and other nanotechnologies to track single-cell images and develop molecular-based drug therapies for cancer. I observed biomedical engineers as they performed experiments in laboratory spaces, worked with data and information at their personal computer work stations, and presented results at regular group meetings. Field notes were written on paper (covering approximately 100 notebook pages) when observing individuals in experimental spaces, but I switched to typing field notes (approximately 300 pages) when observing group meetings or presentations. At the end of most days, I reflected on moments or interactions that stood out to me and then wrote them down so they would not be forgotten. Additionally, on a biweekly basis, my process included writing more formal reflection notes to review what I had observed. My additional data collection methods were informed by these practices and influenced my decision to study biomedical device engineers as well as cellular biomedical engineers.

In addition to the time spent embedded in a medium-sized cellular biomedical engineering laboratory group (14 members), I also visited five additional laboratory field sites (two cell-based; three device-based) that ranged in size from four members to 16 members. These visits included tours of buildings, laboratory spaces, and personal work stations. Some observation sessions were completed over the course of a single day, while others took place over the course of multiple days. Some of the activities I observed were the setting up of

experiments, the analysis of data using algorithms, the capturing of scanned images, informal one-on-one conversations between laboratory members, and a handful of formal subgroup meetings between researchers. Some one-on-one interviews were also conducted during these visits, but the majority took place before or after my official visits. Interviews were conducted primarily off-site due to schedule conflicts or the participant's desire to be interviewed in a more private and confidential setting. The same note-taking procedures were followed, and reflective memoranda were written after each site visit was completed.

Lastly, observation hours were gathered through regular attendance at a university-sponsored biomedical engineering speaker series and by observing the activities and presentations of the annual Biomedical Engineering Society conference. Both the speaker series and the conference served to broaden my perspective and understanding of the field as a whole. Observational notes were taken at all of these events, and insights were incorporated into reflection memoranda and other findings.

All recruited interview participants received an information sheet about the project. Each participant was also required to review and then sign an IRB-approved informed consent form (see Appendix A). Interviews were conducted either in person, over Skype or Zoom, or by telephone. Individuals who participated remotely were asked to sign a digital consent form through the University of Illinois at Urbana–Champaign's secured subscription access to DocuSign. All interviews were audio recorded with participant permission, and participants were asked to either choose a pseudonym for themselves or to approve of one I had preselected for them. All identifying information—including participant names, geographical locations, and university names—was replaced with pseudonyms or anonymized throughout the project. Digital interview files were then downloaded onto a secure server and stored using a numbered system. Interview files were then transcribed into word documents where were also stored on the same

secured server. Participants were given the option to review their transcripts and to request that they be destroyed at the conclusion of the study. Transcripts were ultimately imported into NVivo, where they were qualitatively coded.

Semi-structured interviews were conducted using a protocol of 13 questions divided into four primary areas of inquiry (see Appendix B). The semi-structured approach affords the flexibility needed for knowledge to evolve through dialogue (Kvale, 1996). The protocol was used as a prompt to remember which questions to ask, but given the semi-structured approach, questions were asked in whatever order best suited the conversation. The first interviews were collected as laboratory observation hours were concluding. The majority of interviews were done after all observation hours had been logged. Participants were asked questions about their educational background; current research projects; various laboratory group dynamics; publishing, commercialization, and funding activities; and their feelings regarding disciplinary identities. Additional exploratory questions often asked about the details of various research projects and the perception that participants had about the challenges associated with these projects. A total of 44 individual interviews were completed; they concluded once data saturation was achieved and no new themes emerged from the data (Glaser & Strauss, 1967). The average interview length was 61 minutes, with the shortest lasting 42 minutes and the longest lasting 79 minutes. Any follow-up questions were asked and answered by email. Participants were offered an executive summary of the finished study results in exchange for their participation.

Documents (both digital and print) were analyzed primarily at the beginning and middle stages of this research project. Document analysis is a qualitative method in which the researcher systematically interprets documents associated with a particular topic (Bowen, 2009). In this project, this process began with analysis of the research areas represented in the biomedical engineering departments of R1 universities. Once a university was found to have laboratory

researchers working on the type of novel biomedical technologies discussed in this study, individual laboratory websites were examined in more detail to determine a fit with the project. If applicable, the funded NIH proposals of participant laboratories were found using NIH's research portfolio online reporting tools (RePORT) database. Proposals were reviewed and analyzed for general themes and were especially useful for providing greater detail about projects in which further observation hours were unattainable. Additional documents analyzed during the course of this project include select laboratory publications, company-provided experimental protocols, original and modified laboratory protocols, select presentation slides, and the department graduate requirements for biomedical engineering Ph.D. students.

3.3 Data Analysis

This dissertation project uses a grounded theory methodology in its overall methods of data collection and data analysis. Grounded theory is a qualitative method focused on the discovery of meaning and the development of theory after data are collected (Charmaz, 1983). This approach emphasizes the discovery of meaning and the use of reflective practices throughout a particular project. This approach was chosen over similar methods such as content analysis or thematic analysis, because grounded theory differs from these other methods in many significant ways. For example, in content analysis, researchers primarily focus on a specific context in which to collect data and are more concerned with analyzing content than with analyzing social practices (Mayring, 2004). The analysis portion of the research process is the main thrust of content analysis, and it takes place after all data are collected. Researchers who use content analysis may have prior theories in mind as they analyze data, and this theory-based knowledge likely risks biasing data analysis (Gläser & Laudel, 2013). In the case of thematic analysis, it shares with grounded theory the emphasize on identifying, analyzing, and interpreting patterns of meaning within qualitative data (Braun & Clarke, 2006; 2019). In this dissertation

project, a reflexive thematic analysis was used throughout the coding process.

The benefit of using grounded theory when compared to content analysis or theme analysis is that it provides a systematic way to both collect and analyze study data (Strauss & Corbin, 1994). Kathy Charmaz (1983) asserts that grounded theory emphasizes the discovery of meaning and works toward the development of theory after data have been collected and identified. This approach allows for emergent meanings to appear from the data, and it explicitly avoids making theoretical commitments before and during the research process. One distinctive quality of grounded theory is that researchers engage in reflective analytical practices throughout the project and can make data collection adjustments as needed. For example, in this dissertation project, I started with the goal of observing the laboratory work practices of biomedical engineers who design novel bionanotechnologies.[19] I was aware that this group of people was developing the next generation of healthcare technologies, and I wanted to understand what they valued when engaged in laboratory research and development activities.

In the early-stages of this project, I was unaware of differences between groups working on cell-based technologies and those working on device-based technologies. However, as I observed conversations between laboratory group members at my main field site, and as I gained insights into the discipline by attending lectures and presentations, I became aware of a type of ideological separation between these two groups of researchers. Because of my decision to use grounded theory methodology, I was able to adjust my project and explore this emergent issue by choosing to also study biomedical device engineers.

My initial impressions of biomedical engineering and its associated laboratory practices

[19] After months of observing activities within my main laboratory site I discovered that nanotechnologies are just one type of tool used to study and design cellular technologies. The primary focus for biomedical engineers who use nanotechnologies is to better understand and manipulate cell-level structures and behaviors.

were also shaped by reviewing my field notes and by regularly writing reflective memoranda. One of my first coding activities involved printing my first two months of reflective memoranda, and as I read through each paragraph, I noted in the margins one or two words that described important parts of the passage. The findings from these early analytical activities provided me the tools needed to direct my future observations and to determine how to begin thinking about what types of interview questions to ask. For example, as I continued to review and code parts of my notes and memoranda, the term "translation" began to stand out. Once I discovered that this concept held meaning for this community, it became something I started to see everywhere. However, I also continued to watch and listen and attempted to discern exactly what this term meant. Eventually, this knowledge was used to shape part of my interview protocol and my overall interview approach.

All interview files were transcribed into Microsoft Word documents that were then imported into NVivo qualitative data analysis software. NVivo is intended to help researchers organize unstructured data by allowing them to classify, sort, and arrange information, as well as examine relationships between the data (Swygart-Hobaugh, 2019). Reflective memoranda were also imported into the software as were some select typewritten observation notes recorded during various group meetings. All files were initially coded using an open coding approach, characteristic of grounded theory, which views the process as uncovering ideas and finding meanings (Strauss & Corbin, 1994; Benaquisto, 2008). Codes were applied at the paragraph level, included the use of both *a priori* and emergent terms, and were descriptive rather than analytical. Select paragraphs from this initial round were identified to receive additional rounds of coding, and subsequent codes increased in analytical depth. The average paragraph was recoded between two and four times to finalize code meanings and to streamline the application of codes across all files. A core component of mid- to late-stage data analysis is the continued

application and refinement of codes once all the data have been collected (Kvale, 1996). A final list of codes is provided (see Appendix C), with the number of codes applied per category indicated.[20]

Significant themes were found and refined throughout the systematic coding process. Some late-stage reflective writing activities assisted in the exploration of some of the most important findings based on my total ethnographic experience. These activities also gave me the opportunity to reflect on what the findings suggest when considered within the broader context of values and design research.

3.4 Limitations

The methods used in this dissertation are the same as those used by others who study the laboratory activities of scientific researchers. However, it is not truly possible as a social scientist to enter into any social situation without some idea of the potential meanings and values that may be present in a given space. It is from this position that it might be more appropriate to refer to my study methodology as a modified grounded theory approach. Relatedly, some of the codes applied in this study were, which works more from a theoretically deductive position than from an inductive emergent position. Although the findings of study are largely the result of reflexive and recursive data collection and data analysis approaches, this work recognizes the truly Herculean effort required to enact a pure grounded theory methodology.

As with all ethnographic studies, the results of this project are also not intended to be generalizable. The results are meant to provide insights into the opinions, beliefs, and values demonstrated by individuals and groups who belong to a particular community and as they are situated in relationship to certain social institutions. Although the individuals interviewed for this

[20] However, it should be noted that these quantitative numbers do not correlate to any significant findings related to this study; they are for informational purposes only.

study do provide a useful representation of the laboratories to which they belong, without observing activities in all of the laboratories, and without interviewing all members of each laboratory group, my findings are based on a self-selected group of individuals who may or may not represent all of the values dynamics existent within each laboratory. Some information, however, may prove applicable to other areas where laboratory researchers engage in similar work practices. Laboratories that share a basic science orientation to their research may relate to some of the issues and challenges faced by cellular biomedical engineering laboratories. Similarly, laboratories that take a more applied approach to their research practices may find information about biomedical engineers to be particularly helpful.

My results indicate that more female laboratory members were interviewed than is proportional to the number of female biomedical engineers associated with each representational laboratory. Part of this is due to the fact that one of the laboratories included in this study is composed of all female members, which is highly atypical in any type of biomedical engineering laboratory. The decision for the PI of this group to populate the laboratory with only female members was intentional and is in response to the male-dominated culture associated with engineering in general (Kwak & Ramirez, 2019). This disparity is not believed to impact the findings in any significant way. The values implications highlighted in this project do not suggest that sociopolitical identities serve as a root cause that requires intervention at this stage.

The results also suggest that biomedical engineers in both groups were more likely to participate in interviews if they were of American nationality. This finding was not entirely surprising, as a similar type of avoidance or discomfort concerning participation was noticed among international students when I observed laboratory activities. My approach was to encourage participation among all laboratory members, but I took this dynamic into consideration when interacting with international laboratory members. I believe my approach

recruited more participation among this population of researchers despite the fact that the final participation numbers do not demonstrate equal parity. Although the values implications explored in this project do not immediately point to interventions based on sociopolitical identities, the increased inclusion of non-U.S. laboratory (biomedical or otherwise) group members should be encouraged.

CHAPTER 4: WHAT IS A BIOMEDICAL ENGINEERING LABORATORY?

The characteristics of what describes and defines a laboratory go beyond just the physical structure of laboratory spaces. Laboratories are composed of both social and technical elements that come together dynamically and form a sociotechnical critical unit of analysis. Any cultural analysis of this unit, however, cannot be meaningfully separated from the broader social and political contexts in which it is embedded. University-based biomedical engineering laboratories are actors within the broader cultural narrative of technological innovation and healthcare in the age of neoliberalism. This broader context directly impacts how values manifest and are expressed in laboratory spaces. However, many of these values, such as the desire for more personal recognition, may implicitly implicate other values of moral importance. For example, in the quest to achieve professional praise by receiving a patent, a researcher may choose to preserve their laboratory results as private by not publishing them, an action that stands in opposition to the value of transparency. To make these types of values tensions and trade-offs more explicit, this chapter situates university-based biomedical engineering laboratories within a sociotechnical context.

One strategy used to explore the dynamic structure of a sociotechnical system is sociotechnical interaction networks (STINs) (Kling, McKim & King, 2003; Meyer, 2006). This approach is used in this chapter to identify a relevant population of system interactors that characterize both cell-based and device-based biomedical engineering laboratories. The initial steps used to model a STIN are presented and suggest that both cellular biomedical engineering laboratories and biomedical device engineering laboratories share the same population of interactors. Each laboratory group is also found to be influenced by the same set of core reactors, but the level of this influence is experienced at different intensities. In other words, each type of laboratory relates differently to certain core reactors even though these reactors can be found in

both sociotechnical systems. All of these differences relate to where each group of biomedical engineers initially begins their research and development (R&D) projects along the translational roadmap.

Cellular biomedical engineering laboratories and biomedical device engineering laboratories differ in the type of novel technology they design and where this situates their laboratory activities in the context of translational development. Cellular biomedical engineers design novel technologies yet to be translated for clinical use, whereas biomedical device engineers design novel applications for use with already translated technologies. These different starting points on the translational roadmap (stage T0 and stage T3, respectively) directly impact how each group responds to or anticipates the actions and expectations of various core reactor groups. How laboratories organize their research and develop activities in relation to these core reactor groups shapes the sociocultural base of their respective value systems. It is by first examining these fundamental work practices that a more in-depth analysis of the responsibilities of biomedical engineering laboratories to design ethical technologies comes into view. This examination also sheds light on how and why certain R&D activities take place within each laboratory. This knowledge ultimately supports the argument that more transparency is needed into the laboratory practices of biomedical engineers.

This chapter is presented in four sections. First is a general description of how biomedical engineering laboratories function as sociotechnical systems. This includes step one of modeling a STIN, which identifies a relevant population of system interactors for analysis. The second part highlights how cellular biomedical engineering laboratories, or cell-based laboratories, differ from biomedical device engineering laboratories, or device-based laboratories, based on their relationship to the NIH roadmap of translational medicine. Where cell-based laboratories develop technologies with the hope of translating them one day into clinical practice, device-

based laboratories develop technologies of which the core element has already been successfully translated. The third part of this chapter presents an overview of the standard laboratory activities of cellular biomedical engineers in terms of physical spaces and hierarchical structure. This section also includes a discussion of a cell-based project developing quantum dots (QDs), and uses this to illustrate step two of modeling a STIN by identifying core reactor groups. Lastly, this chapter presents an overview of the standard laboratory activities of biomedical device engineers in terms of physical spaces and hierarchical structure. This section includes a discussion of a device-based software project focused on measuring blood flow in the brain using MRI. This project is used to illustrate step two of modeling a STIN and identifies core reactor groups relevant to biomedical device engineers.

4.1 Biomedical Engineering Laboratories as Sociotechnical Interaction Networks

When adopting a STINs perspective, biomedical engineering laboratories can be thought of as a network of people (including organizations), equipment, data, diverse resources (money, skill, status), documents, legal arrangements and enforcement mechanisms, and resource flows (Kling, McKim & King, 2003). This approach provides a way to understand sociotechnical systems by mapping relationships among elements of the system. This process privileges neither the technical nor the social and understands interactions as dynamic and evolving.

A sociotechnical system may be modeled as a STIN by following steps that begin with identification of a relevant population of system interactors and then with identification of core reactor groups in the system. These steps run akin to the analytical activities associated with the conceptual stage of a value-sensitive design (VSD) approach that provides an overall assessment and evaluation of a system and its values implications. The conceptual stage begins with the identification of the direct and indirect stakeholders associated with a technological design project and their values and then discerns which of these values are implicated as a part of the

design (Borning & Muller, 2012; Milchram, et al., 2018). Laboratories do not work in isolation from outside influences, and interactions among these actors impact the manifestation of values in the laboratory.

The laboratory activities of biomedical engineers are situated within the context of developing and designing technological innovations on a societal level. Although the biomedical engineering laboratories that serve at the center of this study are university-based, they interact with both government and industry actors because of the innovation context in which they work. The relevant population of system interactors for biomedical engineering laboratories is found when examining the triple helix model of innovation. Laboratories may interact with government actors such as funding agencies (e.g., NIH, NSF), regulators (e.g., FDA), or various types of legislation (e.g., property law; patents). Biomedical engineering laboratories that depend on the financing provided by funding agencies must align their research priorities with these agencies to secure funding. Laboratories also consider how to make their innovations patentable (i.e., novel), to protect their property rights, and how to navigate innovation novelty while still appealing to FDA regulations.

Additionally, biomedical engineering laboratories may interact with industry actors such as companies (e.g., Siemens Healthineers), privately funded manufacturers (e.g., Pharmaceutical Research & Manufacturers of America), or publishers (e.g., Elsevier; Springer) who own peer-reviewed journals. Laboratories may rely on private funders in similar ways as government funders and must align research priorities accordingly. Working with private entities, however, may also lead to shared patents and the desire of an industry actor to hold certain data and information as confidential. Biomedical engineering laboratories are also expected to publish research results as a part of their university activities, so they may prioritize projects that are more likely to be published in top-tier journals.

As university-based biomedical engineering laboratories, they also interact with university actors such as their home departments (e.g., biomedical engineering) and the colleges (e.g., engineering) in which those departments are located. The values associated with these actors directly impact how biomedical engineers contemplate their work and its priorities. Researchers may receive certain rewards, such as tenure, if they meet certain expectations (i.e., publications, grants), and junior lab members may strengthen their job marketability if they are associated with the research results of a successful laboratory.

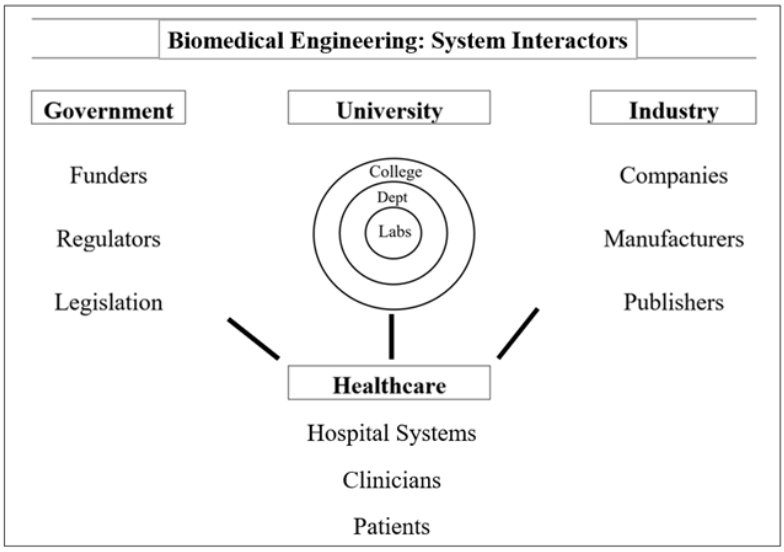


Figure 12

What is missing from a standard triple helix model that is specific to the biomedical context is healthcare as a driver of technological innovation (Figure 12).[21] The key system interactors found in healthcare include hospital systems, clinical practitioners, and patients. Hospitals are responsible for the purchase of biomedical technologies from companies, clinicians use these technologies to treat patients, and patients receive treatment through the application of these technologies. However, healthcare as a system interactor has a direct connection to each of

[21] This assertion touches on step 4 of modelling a STIN which states: identify excluded actors and undesired interactions (Meyer, 2006).

the primary areas of the triple helix. For example, a hospital system (and the actors within that system) may interact with other government, university, and industry actors. Hospitals that have a research a mission may be associated with an institution of higher education, and they may buy their biomedical technologies from companies in the industrial sector. Many of the actors and activities found in hospitals are also regulated by certain governmental laws and policies (e.g., the Health Insurance Portability and Accountability Act, or HIPAA, and the Affordable Care Act, or ACA).

Biomedical engineering laboratories must be understood in relationship to healthcare as a system interactor if the values implications of their lab practices are to be fully understood. The novel technologies developed in biomedical engineering laboratories will eventually impact actors in healthcare regardless of the design priorities of a particular laboratory. For example, if a cell-based biomedical engineering laboratory develops a gene-editing technology without input from clinicians, the future use of that technology by clinicians may be compromised. Additionally, the laboratory may have overlooked a critical element in its technological design that would place the safety of patient treatment at risk. Including healthcare in the triple helix model provides a way to identify whether the wants and needs of actors in healthcare are known (and prioritized) or unknown to a particular biomedical engineering laboratory. Furthermore, this approach provides insight into any undesired interactions that may result from overlooking this category of system interactors.

4.2 Laboratory Relationships to Translational Medicine

The intent of translational medicine is to successfully move scientific knowledge from "bench to bedside" (Wehling, 2015). In 2003, the NIH debuted a five-stage (T0-T4) roadmap of translational medicine that identifies key milestones for biomedical researchers to achieve at each stage of the translational process (Zerhouni, 2003). The manner in which cell-based

laboratories and device-based laboratories relate to the stages of translation differs from each other (Figure 13).

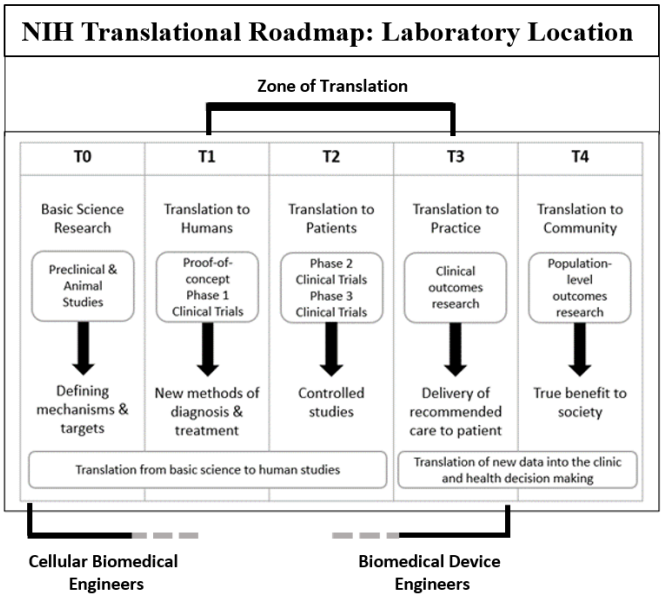


Figure 13

(NIH Translational Roadmap: Adapted from Liverman, et al., (2013))

(Zone of Translation: Adapted from Drolet & Lorenzi, 2011; Page & John, 2019; Simons, et al., 2020)

The promotion of the roadmap among biomedical researchers emphasizes the expectation that their basic scientific discoveries should ultimately result in clinical applications. The translational expectations of the NIH heavily shape the research agendas of biomedical engineering laboratories, since the governmental agency is the largest funder of biomedical research. However, the translational process differs for university-based biomedical engineers because of the type of biomedical technology they develop. For example, the majority of cellular biomedical engineering laboratories have yet to design a technology that has successfully advanced through the *zone of translation* (Drolet & Lorenzi, 2011; Page & John, 2019; Simons, et al., 2020). The zone begins at stage T1 (translation to humans) and extends to stage T3 (translation to practice). The R&D activities of cellular biomedical engineers are primarily located *upstream* at stage T0 of the translational roadmap. However, the situation is different for biomedical device engineers, who develop technologies for which the core element has already

passed through the zone of translation and is already used in clinical settings. Biomedical device engineers engage in R&D activities that are located *downstream* at stage T3 of the translational roadmap.

Although the linear depiction of R&D activities along the roadmap is simplistic, what matters in the context of biomedical engineering is the process stage at which a laboratory is primarily situated. The stage at which a laboratory begins a technological development project provides a critical starting point for understanding the origins of its values.

The values enacted in biomedical engineering laboratories must be understood in the context of where the group's R&D activities are situated along the roadmap of translational medicine. This location directly reflects the type of physical laboratory activities each group engages in and the type of novel biomedical technologies they design. Identifying the core reactor groups of both cellular biomedical engineering laboratories and biomedical device engineering laboratories requires an understanding of the complex and dynamic nature of their technological design practices.

4.3 Cellular Biomedical Engineering Laboratories: Activities and Core Reactor Groups

The laboratory practices that happen here are often referred to as basic research activities by researchers and are composed of laboratory tests performed ex vivo, in vitro, or involve in vivo animal studies (Moreno & Joly, 2015). Cellular biomedical engineering laboratories are located *upstream* along the translational roadmap, but laboratory members often contemplate the potential application (also known as translation) of their laboratory findings early in the technological design process. Even junior laboratory members of cellular biomedical engineering laboratories know the importance of aiming for clinical translation when performing laboratory research. In my interview with Obasi, a first-year Ph.D. student, he spoke about the importance of translation early in the development process.

> Often in our lab we do fairly basic research, but even the basic research is very connected with the thought of translation as a possibility. Even if it's not, even if you don't directly translate it right away, you keep that in mind as you sort of think about what you do. That you want the translation at the end.
>
> (Obasi, Ph.D. student, cell lab)

The goal of translation among cellular biomedical engineers instills a perspective in their laboratories to contemplate research projects as preclinical rather than exploratory, emphasizing the creation of tangible clinical objects (hence the *pre-* designation) versus general knowledge gathering. Although researchers at stage T0 of the roadmap engage in hypothesis-driven research activities, they are less inclined to consider their work as the development of theoretical models, but more as attempts to develop a successful proof of concept (i.e., product). Should a novel cellular biomedical technology advance to stage T1 of the roadmap, indicated by the gray dash on Figure 15 between stages T0 and T1, it will be viewed as making successful progress toward translation (stage T3).

4.3.1 Standard Laboratory Activities

Cellular biomedical engineering laboratories create new processes, new techniques, new methods, and often new materials, and assemble them into *novel systems.* What is unique to these groups of biomedical engineers is that they all use human cells in their work, and they design technologies intended for use at the micro or nano levels. Cellular biomedical engineers work with equipment and materials commonly found in traditional biology or chemistry labs, also known as wet labs, and within these spaces they work with chemicals, drugs, and other biological matter that are tested using liquids (Furubayashi, et al., 2018).

Regardless of the type of novel system developed by a cellular biomedical engineering laboratory—whether it is based on molecular drug delivery, synthetic biology, or genetic engineering—the groups that design and develop these systems are assembled around the same laboratory hierarchy. The average size of a cellular biomedical engineering laboratory included

in this study is 11 members, but the overall size of a group depends on the amount of funding received and the scope of the laboratory's research projects. Since university-based biomedical engineering laboratories are associated with academic departments, each laboratory group member serves in a role primarily determined by their educational and employment status with the university (Figure 14).

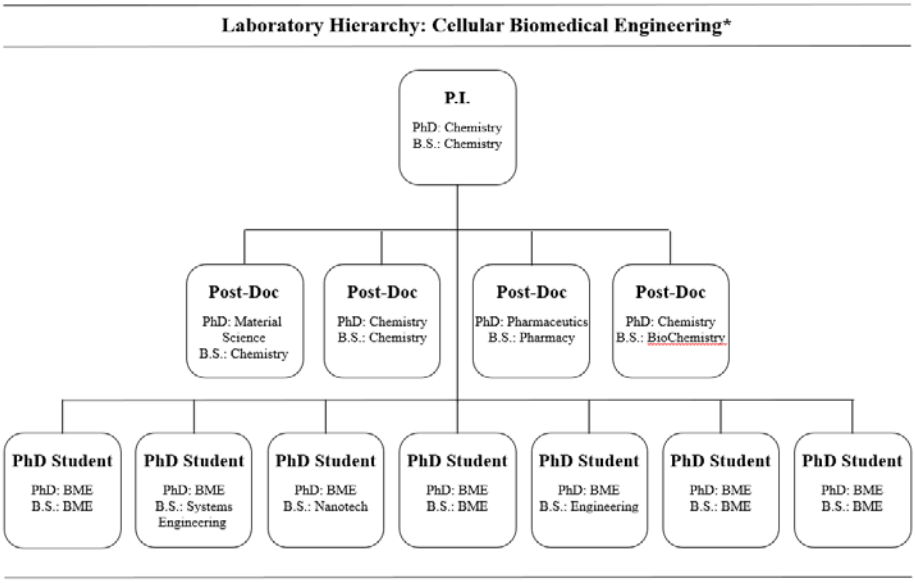


Figure 14
***Example: Tango Lab Hierarchy**

Each laboratory is led by the principal investigator (PI) who is a tenure-track or tenured faculty member employed by the university and who also serves as a professor in the biomedical engineering department. All of the cellular biomedical engineering laboratory PIs included in this study received their Ph.D. in some area of the life sciences (e.g., chemistry, molecular biochemistry, inorganic chemistry) and did their undergraduate training in related areas. Laboratories are also composed of postdoctoral researchers (postdocs) who have earned their doctorates and are employees (non-tenure-track) of the university. Postdocs may be short-term members (approximately one to three years) of a lab group or, rarely, may be permanent members who fulfill scholarly as well as administrative duties. The cellular biomedical

engineering postdocs included in this study have some of the most diverse educational backgrounds (e.g., materials science, pharmaceutics, chemistry, molecular biology) of any group member category. Both postdocs and Ph.D. students report directly to the lab PI, with the latter comprising the largest body of researchers of any biomedical engineering laboratory. Ph.D. students have been accepted into their university's biomedical engineering (BME) program and, as cellular biomedical engineers, share this educational background. More than 85% of these Ph.D. students also have undergraduate training in biomedical engineering or other areas of traditional engineering.[22]

The responsibilities of the PI include selecting and recruiting Ph.D. students, hiring postdocs, publishing research papers, and securing extramural funding. The PI is the person primarily responsible for all laboratory research activities, and group members view their lab PI as the person who "provides the big picture" and teaches lab members "how to tell a story" when writing up results for publication. The moniker PI (versus professor, for example) stems from the fact that a laboratory leader serves as a principal investigator on the grants received in support of the research activities of their laboratory. The majority of a cellular biomedical engineering PI's time is spent promoting the research being conducted in their laboratory through delivering lectures and talks, meeting with current and potential funders, and granting interviews with the press. Laboratory promotion is largely done to meet the expectations of current funders or collaborators as well as to generate interest about the laboratory's research to secure additional funds or collaborators. This type of marketing requires spending significant amounts of time traveling, presenting, and applying for grants. During a conversation with Vincent, a PI of a cell-based lab, I asked:

[22] Where traditional areas of engineering include: mechanical engineering, electrical engineering, chemical engineering, and civil engineering.

Beth: So how much time would you say you spend traveling?
Vincent: In this past academic year, easily 60% of my time was spent traveling.
Beth: Where did you go?
Vincent: Well, I had to go to (Washington) D.C. to meet with NIH folks, and then China to present the findings to some collaborators. I've probably gone back and forth to China at least three to four times this past year. That's not always something I do…but yeah, I'm traveling a lot.
Beth: And then how much time would you say you spend on funding? Like applying for grants, finding potential funders?
Vincent: 80%.
Beth: What? You spend 80% of your time on grants?
Vincent: Definitely. It's tedious, really tedious. And we always need money; we're a growing lab. It's how I pay for my materials and my postdocs. I keep meaning to get them to help with some of these applications…to get them learning how to do it, and how to do it well, but until then…

Vincent's experience of spending significant amounts of time on travel, and on working to secure grant funds, represents what I found to be true when speaking with other cellular biomedical engineering laboratory PIs for this project. Although they are fundamentally responsible for any and all results that come out of their laboratory, the time that PIs spend on travel and grant applications means they are removed from many of the day-to-day operations of their laboratories.

To fill that void, postdocs often step up (albeit informally) to manage the daily leadership functions of the laboratory. They offer guidance to Ph.D. students on many aspects related to the research, such as tweaking part of an experiment, proofreading article passages written by the student, or creating a graph for presenting results data. During my interview with Carson, a postdoc working in a cell-based laboratory, our conversation stopped after only a few minutes when a Ph.D. student knocked on his office door. The student asked for Carson's input about an assay process, for validation about information presented in a data graph, for confirmation that such changes would be acceptable to write about in the journal manuscript, and whether Carson thought the lab PI would approve of all of these changes. After this interaction, I asked Carson if he believed the PI would approve of him giving this level of direction to other laboratory

members, and he replied:

> Oh, would [name of PI] be okay that I just told [name of student] to go ahead with testing that method? Oh absolutely; in fact, he would expect me to do it. I'm here because he knows I'm the expert and can get the work done. He just needs answers; he doesn't need to know this level of how we get the answers.
>
> (Carson, postdoc, cell lab)

The notion that PIs do not need to know the specific details of how experiments are done in the laboratory or how experimental protocols are written or modified, was a perception shared by both postdocs and Ph.D. students. In an interview I conducted with Alan, an advanced Ph.D. student whom I spent many hours observing, he asserted that his PI trusted his work and did not need to know certain details about his research project:

> [T]he truth is that, the specifics of these things, PIs couldn't possibly be in the weeds on every single one of these projects…You know, they can provide broad-level insight, but [name of PI] doesn't know about the preliminaries that I work with, or the base pair compositions of the designs I do, or even the design software I use, or any of the, you know, determinants in that design, or why I went with one option over another option…All these design criteria that are ultimately going to be the main determinants of success, you build this over a long period of time…Nobody could possibly be an expert of all those things.
>
> (Alan, Ph.D. student, cell lab)

Advanced Ph.D. students working in cellular biomedical engineering laboratories have the potential to significantly influence how novel biomedical systems are designed, because, for many, they have a great deal of autonomy when performing everyday research activities in the laboratory. However, this freedom can be granted only by the PI, who does so while retaining the most power and control over the laboratory's broader research agenda.

Laboratory PIs who enable authority on behalf of members of their group are demonstrating trust in the researcher to perform activities in alignment with their expectations. In other words, laboratory members who earn the right to work autonomously do so because the PI deems them to be successfully enculturated into the values and norms of that particular laboratory. Junior lab members (usually first- and second-year Ph.D. students) are rarely given

the same degree of autonomy or authority, not only because they must learn how to do certain lab activities but because they need to demonstrate adherence to the values of the laboratory culture.

4.3.2 Identifying Core Reactor Groups: Example Cell-Based Project

The core reactor groups associated with cellular biomedical engineering laboratories as STINs are found in the realms of government, university, industry, and healthcare. Laboratories developing cell-based technologies perform their research activities in reaction to or in anticipation of these actors and their actions. Because of their primary-stage T0 location along the roadmap of translation, cellular biomedical engineers experience various levels of influence from each of these groups as they design their novel systems.

Core Reactor Groups
Cellular Biomedical Engineers

High	Medium	Low
Gov't Funders (e.g NIH)	Industry Manufacturing	Patients
Publishers	Patents/Licensing	Industry Funders
	FDA	Clinicians

Figure 15

The level of influence each core reactor group has on the laboratory research and development activities of cellular biomedical engineers varies. In this study, I attempt to demonstrate the general level of intensity each core reactor group has on the sample of cellular biomedical engineering laboratories included in this project (Figure 15). What constitutes the categories of “high,” “medium,” and “low” are directional more than conclusive, but they do point toward the general level of influence I believe each core reactor group has on this sample of laboratory participants.

For example, the projects of cellular biomedical engineering laboratories appear to be highly influenced by the groups that provide their funding,[23] and by which results the laboratory believes have the best chance for publication in top-tier academic journals. This suggests that both of these core reactor groups (e.g., NIH funders, publishers) are in the foreground of all or nearly all major design activities in the laboratory. Cellular biomedical engineering laboratories are also moderately influenced by what technologies the group believes might be patentable and by how the FDA may regard their safety and marketability. These core reactor groups (e.g., patents, FDA regulators) may have notable influence on design trajectories but are more likely eschewed if they are found to be standing in the way of achieving funding or publishing goals. Cellular biomedical engineering laboratories are less likely (when compared to biomedical device engineering labs) to receive industry funding, and they rarely reflect on the specific treatment needs of patients or clinicians throughout their design process. The core reactor groups of patients, clinicians, and industry funders rarely impact design activities that constitute their low-level categorization.

Consider these core reactor groups within the context of the following molecular drug delivery R&D project. One of the cellular biomedical engineering laboratories included in this study, referred to here as the Tango Lab, is designing a nanosized drug delivery system to treat cancer on the cellular level. This laboratory responds to and anticipates the actions of a number of core reactor groups as they develop this novel system. In this project, they focus on the design of quantum dots (QDs), which are nanocrystallites (approximately 2–10nm[24]) made of inorganic

[23] Cellular biomedical engineering laboratories are also influenced by thinking about what potential future funders want to see proposed in their research projects.
[24] Nanometers are indicated by the abbreviation “nm”.

semiconductors[25] and have unique optical and electrical properties that make them well suited for dynamic imaging at the single-molecule level. They attach to cells and emit a color frequency based on their size (smaller is brighter; larger is dimmer), the samples of which can be seen when using an electron microscope. The primary aim of this project is that a QD can be paired with a drug-filled nanocarrier to treat individual cancer cells. For example, the nanocarrier could be filled with docetaxel, a chemotherapy drug used in the treatment of breast cancer, which would attach to a cancer cell that the QD found and is tracking.

The motivation for this project came from the PI of the Tango Lab, who learned how to create QDs while working as a postdoc at a previous university. Cellular biomedical engineering laboratories are very involved in developing the type of emerging technologies that STS scholars refer to as *powerful tools looking for uses* (Johnson, 2007). Because of their stage T0 location along the translational roadmap, they often develop technologies in the context of general curiosity, or, in other words, from a basic science point of view. The Tango Lab was just one of the cellular biomedical engineering laboratories working on novel technologies with this type of curiosity-drive origin story. In a conversation with Lorenzo, a cellular biomedical engineering laboratory PI of a different laboratory, he spoke about what initially sparks the motivation to pursue a particular cell-based project in general.

> I think it really varies, even within the same lab, where the new idea comes from. Sometimes you just recognize that, you know, you figured out a way to do something and you go looking for where it's useful…it's kind of, do you start with the hammer, or do you start with the nail?...I'd probably say most biomedical engineering labs are loosely tied to a clinical problem or a need, but I think initially they start with the hammer…I would say that's the way it works for a lot of labs; at the early stage of their work, they have a tool and they go looking for a problem.
>
> (Lorenzo, PI, cell lab)

[25] Their core is most often made using cadmium-based materials which can be toxic to the human body unless the QD is covered in a polymer coating; however, such a coating decreases the strength of its luminescence.

My assumption at the outset of this dissertation project was that cellular biomedical engineers, such as those of the Tango Lab, begin a project based on a clinically defined need or in response to a type of patient illness. While this assumption was not entirely incorrect, the Tango Lab wants to design a system that treats cancer, while the clinical context does not serve as a high or even medium-level influence in terms of the core reactor groups. The dominant driver for cellular biomedical engineers in the development of novel cell-based technologies, such as that of the QD drug-delivery project, is the novelty of the tool itself and the potential it has for earning grant awards and producing publishable data.

The Tango Lab receives the majority of its extramural funding from the NIH. The PI knew when first proposing his research projects that the NIH would view this type of cell-based cancer treatment in a favorable light. As multiple cellular biomedical engineers have suggested throughout the course of this project, “nanosized anything is popular right now,” and “cancer is always a hot topic.” The PI of the Tango Lab has been awarded multiple of the highly sought-after RO1 grants offered by the NIH (NIH, 2019a). The RO1 grants are often awarded in large amounts and bestow a degree of prestige and recognition upon the PI (or co-PIs) who receive them.

The Tango Lab is also strongly motivated by the desire to produce research results that are publishable in high-quality academic journals. One reason is that funding agencies often regard publications as one form of evidence that a laboratory they financially support is making progress. The PI of the Tango Lab was also especially motivated for his laboratory to publish before he received tenure. Having strong research and publication records is necessary in the review, promotion, and tenure process for faculty (Niles, et al., 2020). The PI emphasized the importance of these publications, because “the papers get the grants,” and it is with grant money that “people get the laboratory work done.” Although the majority of cellular biomedical

engineers included in this study expressed strong interest in being published in top-tier, peer-reviewed journals such as Nature and Science, it was Ph.D. students who seemed particularly focused on getting their name on publications.

When these cellular biomedical engineering Ph.D. students were asked why attaching their name to a publication meant so much, they often answered that it demonstrates to others they are knowledgeable and can be viewed more competitively when applying for postdoctoral positions. For many participants, a sense of urgency was conveyed in these statements, indicating a need to achieve a certain number of publications by the time they graduate. This perceived pressure to publish also leads many Ph.D. students to believe a particular number of publications is required for graduation. Approximately one-third of cellular biomedical engineering Ph.D. students included in this study wanted to have a specific number of publications by the time they graduated and believed this was a condition for graduation. However, closer examination of the departmental graduation requirements revealed that none of the biomedical engineering Ph.D. programs represented in this study, in fact, require any publications before graduation. This internalized pressure to publish may indirectly or directly influence aspects of the design process as performed by the largest group of individual researchers involved in the project.

Since the goal of cellular biomedical engineering laboratories is to advance their R&D projects along the translational roadmap, they often contemplate what is needed to advance a project to the next (T1) stage. For example, as the Tango Lab performs experiments to determine what QD type is the brightest, what core material works best or is the safest, and what type of publishable data can be produced, the primary aim is to test QDs with the most promise (i.e., smaller, brighter, controllable) in vivo using animals. In fact, the Tango Lab recently began some animal studies with the hope that those promising QDs will continue to function well and can be paired with drug-filled nanocarriers. If successful in vivo tests of the QD nanosized drug system

are proven, which has yet to happen, then the laboratory will have achieved a valid proof of concept and the project will have advanced to the T1 stage of translation.

Although no QD nanocarrier drug treatment systems for cancer have undergone any phase of human clinical testing, cellular biomedical engineering laboratories such as the Tango Lab will likely need to anticipate what comes after a successful proof of concept is achieved. In addition to responding to the high-level core reactor groups, such as the NIH and academic publishers, the Tango Lab also must anticipate what three future translational core reactor groups (stage T1 and beyond) might care about in relation to these novel systems. First, such labs will contemplate aspects of their design that may be more or less patentable by the U.S. Patent and Trademark Office with the hope that such patents could be used to attract industry actors. Second, cell-based labs want their technology to be licensed to a manufacturer that will then take over the next development steps, including clinical trials, FDA approvals, and upscaling the manufacturing process.

Lastly, in anticipation of this development transfer, cell-based labs may also consider what the FDA is more likely to approve in terms of the design of the novel system. For example, in the case of the Tango Lab, the core material of a QD is made from a heavy metal (cadmium selenide) that is toxic to the body and would not receive FDA approval. Therefore, the Tango Lab made the decision to cover the QD using a polymer coating that is believed to be safe for human use. The lab also decided to pursue testing of a glucose-based nanocarrier that recently received approval for human use in another country. These design choices were all made in anticipation of what the Tango Lab believes the core reactor groups would want to see to ensure that this novel system is clinically translatable.

The laboratory R&D activities of translational stage T0 cellular biomedical engineers are influenced by a number of core reactors groups during the design process. The intensity with

which cell-based laboratories respond to and anticipate the expectations of each group impacts their project priorities. The same core reactor groups also influence the R&D activities of biomedical device engineering laboratories; however, each is experienced at different levels of intensity.

4.4 Biomedical Device Engineering Laboratories: Activities and Core Reactor Groups

In this section, the laboratory activities, roles, and responsibilities of biomedical device engineers are presented. Included is a discussion of a specific MRI technology that is under development and is used as an example to identify core reactor groups found in biomedical device engineering laboratories. In contrast to cellular biomedical engineering laboratories, biomedical device engineering labs are primarily situated at stage T3 (translation to practice) along the roadmap and work with technologies that are already regularly used in clinical settings, such as MRI machines, ultrasound devices, and prosthetic apparatuses. They describe their laboratory practices as optimizing or improving upon these devices through the design of *novel applications.* Working with technologies that have already, in some way, made the successful translation into clinical practices provides a sense of pride for biomedical device engineers. One interview participant, Shui, referred to her biomedical device laboratory group as conducting translational research because they were simply making technical changes to prosthetic devices that are already used by patients.

> Our work is not very basic science, we are very translational…so when I say I'm making technical changes, designing the hardware, software, and things like that…we're just making a slight difference to that technology and using it on humans. That's what makes it translational, compared to studying the mechanism of DNA transcription or something, where that next step would be (pauses), I don't even know, but the next step wouldn't really be like directly benefiting people, so that's not really translational.
>
> (Shui, Ph.D. student, device lab)

Biomedical device engineers often think of their technological design activities as just *optimizing* or *improving* an already existing device. This perspective remains even when

researchers engage in heavily data-driven research activities that guide how to build new physical accessories or develop new diagnostic software models. This view is, in part, reinforced by the fact that very few optimized or improved biomedical devices need to revisit the phases of clinical testing found at stage T2 of the translational roadmap. However, some novel biomedical devices, such as those labeled by the FDA as "software as medical devices,"[26] may need to revisit some type of clinical testing (as indicated by the gray dash on Figure 15 between stages T3 and T2). However, the majority of novel devices designed by biomedical engineers are not required to engage in multiple phases of clinical testing.

4.4.1 Standard Laboratory Activities

The technological alterations made by biomedical device engineers fall into two camps of laboratory research activity: making changes to the physical medical device itself, or developing new models to better understand certain physiological phenomena. These laboratories work in spaces conducive to using mathematics, physics, and computer science to model simulations of complex systems in response to changing conditions (Brodland, 2015). Additionally, some biomedical device engineering laboratories may work with people and perform volunteer studies composed of data collection activities, movement studies, imaging tests, and possibly clinical trials. Similar to cellular biomedical engineers, they develop testing protocols and keep track of the changes they make along the way. However, these protocols may be considered proprietary, depending on whether a private company funds a particular project, and are made inaccessible to others not included in a nondisclosure agreement (NDA).

Before I made my first site visit to an MRI imaging laboratory, I had spent months

[26] The term software-as-medical-device is used by the FDA in the regulation of devices; defined as: "software intended to be used for one or more medical purposes and perform these purposes without being a part of a hardware medical device." (FDA, 2018a)

observing the everyday activities of a cell-based biomedical engineering group. My comfort with referring to experiments as performed in vivo or in vitro had increased, so I visited this MRI lab feeling confident that I knew, to some degree, what I was talking about. During my initial tour of laboratory, I asked of my tour guide, a postdoc in the lab:

> **Beth:** So at what stage of development would you say your research is at?
> (long awkward pause)
> **Ivan:** What are you asking?
> **Beth:** In your experiments, or other people in the lab's experiments, are you working with things in vivo, ex vivo, in vitro?
> (another long, awkward pause)
> **Ivan:** No, no, no, that's not here, we don't have a wet lab. We are a *dry lab*.

Ivan's answer was initially quite confusing to me, as I had never realized there was a difference in types of scientific laboratories, especially among researchers who work in the same discipline. The response given by Ivan was an early indication that biomedical device engineers function in a very different day-to-day laboratory reality than those who work with cell-based technologies.

Dry labs are places where computational or applied mathematical analyses are done with the assistance of computer-generated models (Lendvay, et al., 2013). Computer systems in these biomedical engineering environments are the primary drivers in analyzing and evaluating biological data. The biological data used in these models and simulations come from either outside collaborating groups or are from the data collected when a laboratory performs volunteer studies with participants (Bhanot, et al., 2017). Through the use of many different methods and algorithms, these systems produce simulations and create models used in the diagnosis and treatment of physiological diseases. These models may be built as stand-alone applications or those to be used in conjunction with specific physical devices.

Moreover, biomedical device engineers may build device hardware accessories in addition to the software they develop. Sometimes, this results in spending a significant amount of

time encouraging the two systems to speak to one another. As one Ph.D. student explained to me when discussing her current MRI project, “I spent all my time debugging the machine because I needed it to recognize input from my sensor”; she added that she had to get “the hardware and software to work together.” When walking through a dry laboratory, it is likely that one will see workbenches off to the side that are used to design a variety of electronics, for fabrication purposes. There are also many areas used for the storage of dry materials and smaller pieces of mechanical equipment. Particularly well-funded biomedical device engineering laboratories may also have access to entire MRI machines that may be housed in their laboratory space. Such a configuration requires placement of the machines behind security doors and implementation of additional safety measures to protect laboratory members and any study participants. Laboratories that house these machines often share them with other lab groups on campus that pay for this time and access. However, the benefit of this situation, according to a biomedical device laboratory PI I interviewed, is that prevents other laboratories from “spending a whole grant on a single piece of equipment.”

Regardless of the type of novel application developed by a biomedical device engineering laboratory—whether it is based on MRI, ultrasound, or prosthetic technology—the university based groups that design these applications are assembled around the same hierarchy as cellular biomedical engineers. The average size of a biomedical device laboratory included in this study is seven members. Group members also serve in roles associated with their academic and employment status (i.e., PI, postdoc, Ph.D. student), and their responsibilities by career stage are similar to those found in cellular biomedical engineering laboratories.

The educational backgrounds of biomedical device engineers are strongly based in engineering (i.e., mechanical, electrical, or biomedical), and many postdocs and PIs have backgrounds in physics. The PIs leading biomedical device engineering laboratories have

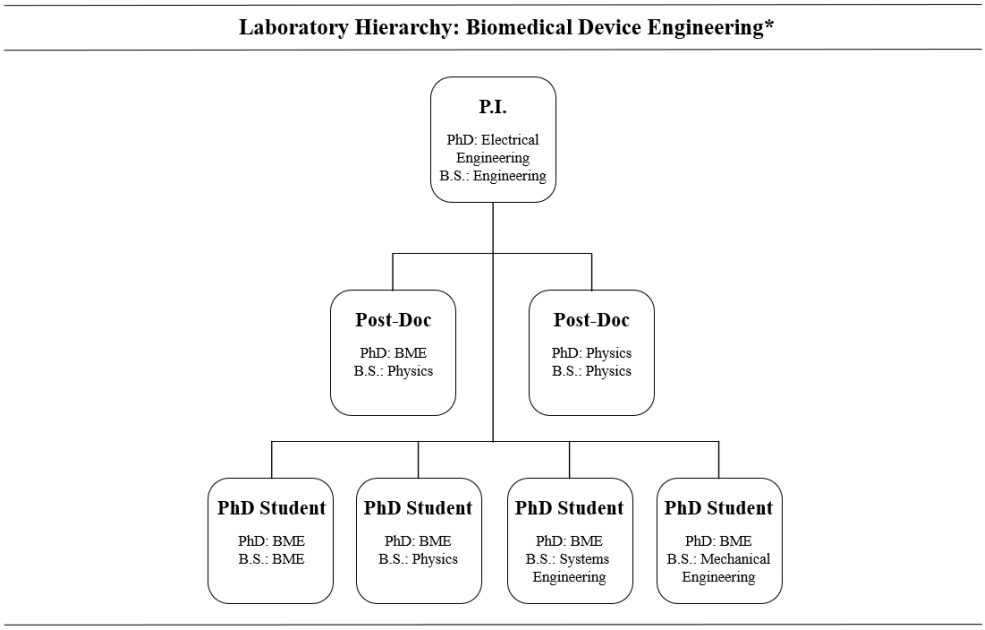


Figure 16
***Example: Bravo Lab Hierarchy**

doctorates either in physics or, in the case of the Bravo Lab (Figure 16), in electrical engineering. Postdocs working in biomedical device laboratories may also have engineering backgrounds, but what is notable is how many have an educational background in physics. Given the smaller size of these laboratory groups, postdocs often fulfill highly specific knowledge-based gaps in a current project, and training in physics appears to be in demand. Ph.D. students may also have backgrounds in physics, but it is more likely they have undergraduate training in the traditional areas of mechanical or electrical engineering. Increasingly, Ph.D. students enter biomedical engineering doctoral programs with undergraduate degrees in biomedical engineering itself. However, as expressed to me by multiple postdocs in biomedical device engineering laboratories, there is a concern that such undergraduate training "won't give them the math skills they need" to produce high-quality research.

The benefit of a shared educational background in engineering, however, is that these laboratory members have a common epistemology. Central to engineering curricula is the principle of design that teaches engineers to contemplate how to systematically approach a

design problem. Students learn the need-know-how method about what is required to solve a problem, what they know about it, how to design for it, and then how to actually solve the problem (Kosky, et al., 2013). It is about collecting information and designing something that fits the system, or in other words, solves the problem. Kamala speaks to this ability as characteristic of an engineering identity.

> That's the part that I'm really motivated by, is kind of synthesizing new information from the lab…. but then turning it into something else…it's characteristic of being an engineer, is looking at the facts and then designing something that is suitable to tell that system.
> (Kamala, Ph.D. student, device lab)

Although postdocs with degrees in physics, a heavily math-centric discipline, may be concerned about the lack of mathematical training of biomedical engineering students, the principle of design approach strongly requires the use of math throughout the design process. In fact, both math and data are considered defining characteristics of what drive engineering (Salter & Salter, 2017). Those who rely on design principles when engaged in biomedical device laboratory activities come to value what this suggests for their engineering capabilities.

> I think for my four years in undergrad it was very much focused on the engineering design process and using math to get the answer, so that part is not so hard for me. So I just spend extra time now making sure that the science is as strong.
> (Fahad, Ph.D. student, device lab)

There is a comfort level among biomedical device engineers that their engineering skills are robust along with an understand that their scientific knowledge—in this case, where science means biology—needs further development. The manner in which this biological information gap is addressed, however, varies greatly among biomedical device engineering laboratories.

4.4.2 Identifying Core Reactor Groups: Example Device-Based Project

The core reactor groups associated with biomedical device engineering laboratories as STINs are the same as those found in cellular biomedical engineering; however, the intensity level manifested by each influential group in the biomedical device engineering laboratories

included in this study is experienced differently. Biomedical device engineers react to or anticipate these core reactors based on their primary stage T3 location along the translational roadmap. This starting location for the R&D activities of these laboratories changes how the level of influential intensity for each core reactor group is experienced by the lab (Figure 17).

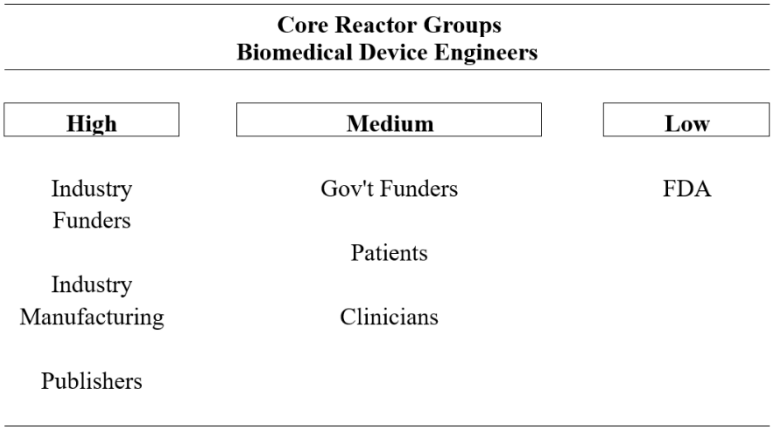


Figure 17

For example, all of the biomedical device engineering labs included in this study received research funds from private (i.e., industry) funders (e.g., Siemens Healthineers). This was often the case because biomedical device engineers work in some capacity with already translated technologies. Therefore, the influence of these funders, who were often the product manufacturers as well, guides the direction of a laboratory project. However, when compared to the level of core reactor group influence experienced by cellular biomedical engineering laboratories, industry funders do not influence many of the projects considered in this study. Nevertheless, where biomedical device engineering laboratories also experience a high level of influence from industry manufacturers, cellular biomedical engineers experience that only at a medium level insofar as they contemplate how to make their developments attractive to industry entities that want to upscale production. Biomedical device engineering laboratories also experience less immediate influence on their projects based on the expectations of government funding agencies when compared to cellular biomedical engineers. The influx of industry

funding into biomedical device engineering laboratories makes them less dependent on securing government funds to move forward with their projects.

Furthermore, biomedical device engineering laboratories have more access to clinicians and patients than do their cellular biomedical engineering counterparts. Since many biomedical devices are already used in a clinical capacity, clinicians can speak to certain proposed design considerations. The input of patients might also be more readily available, as biomedical device engineering laboratories are more likely to sponsor volunteer studies of devices in the research spaces. However, both clinicians and patients are ranked as only moderately influential to the laboratory activities of biomedical device engineers because of the way this group of engineers interacts with physiological and clinical information in technological design projects. Publishing as a high-level core reactor group is shared with cellular biomedical engineering laboratories, as both types of laboratories consider how and where their research results could be published.

Lastly, there appears to be less influence coming from the anticipation of what the FDA might want to see in certain biomedical device engineering projects. This stands in contrast with cellular biomedical engineering laboratories that often contemplate the FDA as a part of the design process. The general notion among biomedical device engineers is that the core biomedical device technologies they work with are already FDA-approved, so this factor serves as less of an influence for a core reactor group. Next, these core reactor groups are considered in the context of the following MRI brain blood flow R&D project.

One of the biomedical device engineering laboratories included in this study, referred to here as the Bravo Lab, is designing a nuclear-based methodology to measure blood flow in the brain using an MRI machine. In this project, the lab is developing an MRI technique that measures blood volume as it flows through the back of the brain in individuals who have some type of vertebrobasilar circulatory disorder. Such disorders could be caused by narrowing,

blocked, or ruptured blood vessels, and individuals with these disorders are at greater risk for a stroke, transient ischemic attack (TIA), or cerebral aneurysm. The aim of this project is the design of an interpretable diagnostic model that supports physician decision-making when using MRI technology in clinical environments. For example, if a patient experiences the symptoms of a vertebrobasilar circulatory disorder—such as slurred speech, limb weakness, or balance issues—their brain blood flow could be measured using this new nuclear-based treatment in hopes of a more speedy and accurate diagnosis of their medical condition.

The origin of this project came from Siemens Heathineers, an international corporate medical technology company. Siemens approached the Bravo Lab, with funding, to work on this project based on an already-existing working relationship between the laboratory and the company. The Bravo Lab also regularly uses one of Siemens' specialized MRI machines to conduct a variety of laboratory experiments. One of the most significant technical goals of this project is to build a new detector that enables this nuclear-based method of measuring blood flow in the brain. The most pressing challenge at the moment is designing software that allows data received by the new detector to be readable by the MRI machine.

> Right now I'm building a new detector…so the thing is that our instrumentation is working on compatibility between this and our new nuclear imaging technique. So it's one that uses a higher energy radiation…so the detector needs to be compatible…we are working to improve the consistency of how [the MRI] it reads the technique.
>
> (Stefania, postdoc, device lab)

One of the benefits of working directly with the company that also manufactures the MRI technology is that group members more readily gain access to the tools and data needed to build the new application. However, in the course of this project, the lab has also needed to test the new method and collect additional data from patient volunteers. Working with people provides unique and important data that are needed to build the technology, but it also introduces a source of frustration among Ph.D. student laboratory members who want to increase their publication

numbers before they graduate.

> It can be very frustrating because these studies take a lot of time. It's not a very, let's say, publication-friendly study. So in different labs where you are dealing with biomaterials, you can do experiments as quickly as possible and you bump up your publication numbers…but in my case, because I always have to deal with people, in some cases it can take months….the impact factor [of the journal] would be probably on the high side, but it takes time...so it's not, let's say, a quantitatively oriented study (laughs).
>
> (Bharat, Ph.D. student, device lab)

In my conversations with Bharat, he never spoke about making changes to his research activities because of the length of time needed to complete the testing, but he was always aware of how project changes made by his lab PI would delay submission of a publication with his name on it. Bharat was one of just two Ph.D. students included in this study who was working in a biomedical device engineering laboratory and wanted to pursue an academic faculty position after graduation. The majority of biomedical device engineering Ph.D. students said they hoped to find employment in industry (companies) because of expectations for higher pay and the perception that such environments would be less stressful because of a reduced need to secure funding and grants to support their laboratory research.

The Bravo Lab also includes a number of informal and formal university-level collaborators on the brain blood flow nuclear imaging project. Laboratory members occasionally consult with a kinesiologist on campus who provides knowledge regarding muscle movement and blood flow—knowledge that no one in the Bravo Lab currently has. In exchange for this knowledge input, the Bravo Lab provides the kinesiologist with access to its testing data for his own research purposes. However, the kinesiologist was asked to sign an agreement with Siemens that established terms about what parts of these data could be used for local research purposes and what data could not be shared in any resultant publications. Siemens, as the primary funder of this project, owns the software and testing data that are created and managed by the Bravo Lab. However, Siemens is also open to making exceptions about who shares ownership of the

data and with how those data may be used for academic and educational purposes.

Additionally, a clinical collaborator is involved in the nuclear brain blood flow project who actively participates in laboratory group meetings (approximately once a month) and regularly refers patients for participation in laboratory testing. The clinician provides critical knowledge about the neurological function of the brain, which assists the Bravo Lab in making informed design decisions. However, the clinician himself does not provide direct technical input into how the technology should be built. For example, the clinician does not know how the new reactor will be technically integrated with the core MRI device. As one Ph.D. student of the Bravo Lab commented about this collaborator, "He doesn't need to know *how* it works, he just needs to know *that* it works. It's up to us to explain it to him, but he doesn't seem to listen."

4.5 Laboratory Differences by Characteristic

Characteristics of Biomedical Engineering Laboratories	
Cellular Biomedical Engineers	**Biomedical Device Engineers**
Cell-Based	Device-Based
Wet Labs	Dry Labs
P.I. Background: Life Sciences	P.I. Background: Engineering
Preclinical Technologies	Clinical Technologies
Upstream on Roadmap	Downstream on Roadmap
Pre-Translational	Post-Translational
Novel Systems	Novel Applications

Figure 18

Biomedical engineering laboratories differ in many ways (Figure 18). They design different types of technologies, work in different laboratory environments, their members have different educational backgrounds, and each type of group relates differently to the process of translation. These differences reflect and influence how values are enacted in the laboratory. Biomedical engineering laboratory groups do, however, share the same core reactor groups, but the level of influence each reactor group has on laboratory R&D practices differs in level of

intensity (Figure 19).

Level of Core Reactor Group Influence by Type of Laboratory			
Type of Lab	**High**	**Medium**	**Low**
Cell-Based	Government Funders Publishers	Industry Manufacturing Patents/Licensing FDA	Patients Clinicians Industry Funding
Device-Based	Industry Funders Industry Manufacturing Publishers	Government Funders Patients Clinicians	FDA

Figure 19

All of these differing characteristics tell an important story about how values develop in biomedical engineering laboratories that design novel technologies. In Chapters 5 and 6, the values of cellular biomedical engineering laboratories and biomedical device engineering laboratories are discussed in greater detail, respectively, with both explicit and implicit values found in each type of laboratory group identified. The implications of enacting these values in the laboratory are considered, and these chapters demonstrate how the values of both responsibility and transparency are implicated by the laboratory practices of both groups of biomedical engineers.

CHAPTER 5: CELLULAR BIOMEDICAL ENGINEERS

Cellular biomedical engineers are upstream researchers along the translational roadmap, and this location significantly influences the shape of their laboratory R&D responsibilities. This distance from the clinical context ensures that cellular biomedical engineers envision others, not physicians nor patients, as the perceived end users of their laboratory developments. While biomedical device engineers recognize that their novel technologies will be used with patients, cellular biomedical engineers resist describing their developments as technologies and are unsure about who will be the ultimate end user. The assumed end users become those actors that cellular biomedical engineers expect to encounter first as they advance along the translational roadmap. Since many novel cell-based technologies are decades away from clinical use, the next actors along the translational pipeline are from industry and government sectors. Cellular biomedical engineers seek to identify industry partners that will take over the marketing and production of their laboratory innovations, and these industry actors want to see innovations that have the best potential for FDA approval. These design goals create a disconnect between what technologies are designed by cellular biomedical engineers in the lab and what patients need to receive safe and effective clinical care.

Cellular biomedical engineering laboratories and biomedical device engineering laboratories do share the problematic characteristic of implementing practices that engender distancing between themselves and the reality of clinical healthcare practices. Whereas the actions of biomedical device engineers lead to distancing through design activities that transform biological processes into abstract representations, cellular biomedical engineers are distant from the places and people who will one day use the novel biomedical technologies they develop. Biomedical device engineering laboratories have access to physicians and patients, because of their location along the translational roadmap, in a way not experienced by cellular biomedical

engineering laboratories. This lack of access and exposure to critical healthcare actors limits the type of information that cellular biomedical engineers receive. Having more information is especially critical for researchers at the T0 stage of translational development, because they have the most power at this early to stage to design for safer and more effective novel cell-based technologies. The laboratory design practices of cellular biomedical engineers suggest values implications for the future use of novel cellular biomedical technologies.

This chapter argues that the laboratory R&D activities of cellular biomedical engineers present implications for the values of responsibility and transparency. These activities limit the awareness that researchers have of their responsibilities as designers of technology. Cellular biomedical engineers also engage in laboratory practices that decrease the transparency that others outside the laboratory as well as future researchers will have about their experimental methods. These arguments are presented in the following three sections. First, cellular biomedical engineers resist labeling their laboratory developments as technological developments, and this semantic distancing is the result of their physical distance from healthcare settings. Therefore, cellular biomedical engineers do not recognize their role as designers of technology, which limits their perception as responsible actors in the ethical development of novel biomedical technologies.

Second, cellular biomedical engineers identify primarily as scientists, but the location of their laboratories in colleges of engineering results in their internalization of values and goals more often associated with that discipline. This includes a desire to be seen as problem-solvers and as being focused on producing a translatable product. Unfortunately, as cellular biomedical engineering laboratories increasingly focus on establishing start-up companies, securing patents, and pursuing industry partnerships, they become even further removed from the healthcare context. This misalignment between the values associated with engineering and the values

associated with science results in conflated meanings for the terms “translation” and “impact.” Translation comes to mean marketable instead of clinically viable, while impact comes to mean journal impact factors (and influential scientific knowledge) instead of being impactful to the health of patients. These conflated meanings obscure what cellular biomedical engineers actually mean—and therefore actually value—when performing laboratory activities.

Lastly, cellular biomedical engineers want to think of the laboratory innovations they develop as translational; in so far as that what is developed in their lab will ultimately be used in a clinical context. The reality, however, is that even for those innovations which show the most promise, they are still 10-20+ years away from regular clinical use. Additional actors (e.g. industry partners, FDA) are introduced into the development process during this time and their expectations ultimately serve as those which cellular biomedical engineer laboratories want to meet. Ultimately, cellular biomedical engineers plan to transfer responsibility of the development of a technology to industry partners well before they are ready for clinical use. The result is laboratory design innovations which appeal to these immediate actors and lose sight of patients as the end-user. This emphasis on non-patient actors risks the development of cell-based technologies which implicate the safety of human well-being, and creates an incomplete picture of who is responsible for designing trustworthy biomedical technologies.

5.1 When is Something a Technology?

The use of the term “technology” in cellular biomedical engineering laboratories carries a great deal of political meaning. Laboratory groups that decide to label their novel cell-based systems as a technology—instead of a “method” or a “technique”—do so in an attempt to signify a values alignment with outside interests. In my conversations with cellular biomedical engineers, they expressed knowing there is an expectation in the field that they develop a technology as members of an engineering laboratory. They regard engineers as the people

responsible for the development of technologies because such developments offer some type of utility for society. However, during many of the interviews, with junior cellular biomedical engineers in particular, they expressed feeling more comfortable referring to their laboratory developments as methods or techniques than as technologies. In an interview with a member of the cell-based Tango Lab, who uses QDs to study the behavior of single cells in her research, I asked how she would define what she was developing.

> What do you call mine, I'm not sure about technologies per se…so it's a new, like using a new quantum dot, so that's new chemistry (pauses), a new imaging platform, and new analysis processes combined (pauses), and it's not technology, it's like a platform, but it's not like a machine.
>
> (Mai, Ph.D. student, cell lab)

The difficulty Mai had in answering this question was not a surprise. In a laboratory group meeting I attended a few months before this conversation, Mai delivered a practice conference presentation in front of the group. She repeatedly referred to her work as developing a new method in the use of quantum dots to study breast cancer cells related to the NFkB pathway. After she used the word "method" four to five more times, the PI of the laboratory eventually interjected, "No Mai, it's a platform. It's a technological platform. You keep saying method, but this platform is for universal cell tracking." Mai and the PI continued to discuss the details of this technological platform for the next few minutes, but what stood out to me was the emphasis the PI placed on the word "technology." Why was this such an important term for him to have associated with the research coming out of his laboratory?

Referring to a cell-based laboratory development as a technology implies to outside groups, such as the NIH, that the item holds the promise of clinical utility. Shortly after the exchange between the PI and Mai, I asked the PI why he preferred the use of the term technological platform over that of method. He chuckled lightly and answered, "Part of this is political, you know, have a fancy name and it stands out. Funders like to hear that kind of stuff."

What the PI was referencing was his recent NIH grant application in which he refers to the individual cell-tracking part of the laboratory's QD drug delivery system as a technological platform. As a platform, this part of the system could be used on a broader scale to track any type of cell, not just cancer cells. Adding the label of technology suggests to the NIH grant reviewers that there is also the promise of clinical utility. If this part of the system was referred to as a method versus a technology, its broader utility would be less immediately apparent. Use of the term technological hints at the translational potential of the tool under development.

The cellular biomedical engineers included in this study also recognize that government funding agencies like to share the language included grant applications to communicate with the public. During an interview with a participant from a cell-based laboratory, which was developing a similar system to that of Mai's group, I asked if her laboratory also used the term technological platform to describe their developments.

> We're trying to communicate to people who are not necessarily in our field but are impacted by our field, and this is just the everyday person who is not necessarily inside of science or engineering. I think sometimes we feel like we need to use language that will excite them, or they'll understand, oh, this is new technology, it's very fancy, it's very cutting-edge. It kind of elicits these feelings and emotions and perceptions from people who are listening to us.
>
> (Jiayang, Ph.D. student, cell lab)

The intent behind using the language of technology to describe novel cell-based systems is less about cellular biomedical engineers recognizing their roles as designers of technology but more about marketing the clinical potential of their laboratory developments to outside interests. Assignment of the technology label serves as a signifier to outside groups, such as the NIH, that the laboratory's values align with the values of the funder and the message that funder group seeks to convey to the public. In other words, the NIH values clinical translation, so it ideally wants to provide financial support to laboratory projects that have the most potential to be successful in translation. Cellular biomedical engineering laboratories that speak directly to this

value in their grant applications demonstrate a value alignment in hopes of increasing their competitiveness.

Although a laboratory might affix the technology label for political or marketing purposes, this action does not necessarily convert cellular biomedical engineers to the belief that they are designers of technology. Part of the reason they hesitate to acknowledge this role is that what they consider to be biomedical technologies are device-based and not cell-based. In an interview with a first-year Ph.D. student working in a genetic engineering laboratory, she told me she did not consider her research to be developing a technology because it is different than her concept of what constitutes a biomedical technology.

> [T]hat's one of the things that I don't fully know. I'm still trying to figure out what quantifies something as being biotechnology. People have referred to using the CRISPR-Cas9 as a *wonderful source of biotechnology* (laughs), and that just seems so vastly different in my opinion to someone referring to biotechnology as a prosthetic limb.
>
> (Julia, Ph.D. student, cell lab)

In my conversation with Julia, she explained how a prosthetic limb is a technology because it is used by patients to treat a clinical condition. The majority of biomedical engineers included in this study, both cell-based and device-based, drew a clear line between researchers who develop devices and those who develop cell-based systems. Those who develop devices are designing technology, but those who develop cell-based systems are designing something else.

The recognition of *when* biomedical technologies receive that label also correlates to when that technology is used outside of the laboratory environment. In my interview with Oleksander, the oldest participant in this study with 30-plus years of experience working in three cell-based laboratories, he presents a distinction between what constitutes a technology and what constitutes a method. He suggests that the label changes once something is used outside of the laboratory; however, he implies that this line of *when* has also changed over time.

> So with methods, it's like a protocol, to do some experiments. For example, there is a

> method which I do called gel-electrophoresis, this is a very common method to separate DNA with electrical currents through the gel, it is a method, but it is also a technology. But people nowadays when they talk about technology I think they assume it is applied outside of the lab. [Beth: Okay]. So yeah, it's outside of the lab, but whatever you use inside the lab it's a method. So when you discover something new which can be used outside of labs, that is a kind of technology.
>
> (Oleksander, postdoc, research scholar, cell lab)

Many changes have taken place since Oleksander first began his cell-based research program in the late 1980s. Most notable are those associated with the Human Genome Project and the prominent conceptualization of translational medicine in biomedical research. The completion of the HGP convinced researchers that human diseases could be linked to our genetic code, the promise of which suggests that fixing the gene will lead to a cure (Stevens, 2013). As evidenced in this study, genetic engineers are not the only biomedical engineers who design potential treatment interventions on the cellular level. In many ways, advancing cell-based treatments to market is an open frontier, so the race to develop the next amazing technology—with the fame and money that comes with it—is underway (Leuty, 2019).

Proponents of translational medicine also emphasize the differences between preclinical research activities and clinical research activities. Cellular biomedical engineering laboratories learn to consider their laboratory developments as those that are preclinical within a translational framework. Since translation emphasizes the importance and value of clinical technologies, cellular biomedical engineers come to understand that preclinical technologies have less value than technologies used in the clinic. The value of a technology is only given to laboratory developments by those who have the power to do within the context of translation. Those who have this power from the perspective of cellular biomedical engineering laboratories are commercial and governmental entities that determine when a development is marketable and ready for clinical use. The suggested values implication from this is that preclinical technologies, given their location within the laboratory, have less potential to result in negative impacts.

Cellular biomedical engineers perceive having less responsibility to anticipate, and design for, these potential impacts. The boundary of the laboratory walls serves as a way to sidestep questioning the implications of a technology until it transcends those walls. Consider this issue further within the context of the CRISPR-Cas system. This technology is regularly used in genetic engineering laboratories, is used in only a handful of FDA-approved clinical treatments, but is also commonly referred to as a technology by cellular biomedical engineers.

5.1.1 What is a Biomedical Technology?: The CRISPR-Cas System

All of the genetic engineering laboratories included in this study use the CRISPR-Cas system (CRISPR for short) in their research projects. This system has become so common in cellular biomedical engineering laboratories that it is on par with other laboratory equipment such as microscopes and hot plates that simply fade into the background. The interesting notion about CRISPR, however, is that very few clinical treatments involving its use have been approved around the world (Stein, 2019). Additionally, those that have been approved remove only a part of a defective gene, since we do not yet know how to replace or rebuild parts of our genes with new information (Mittal, 2019). The use of CRISPR is largely relegated to the realm of the cellular biomedical engineering laboratory where it has been used since it was first developed, and patented, in 2013.

The most commonly used part of the system is the Cas9 component developed by American biochemist Jennifer Doudna and French biochemist Emmanuelle Charpentier.[27] The technology was first presented in a 2012 issue of Science (Jinek, et al., 2012), and since then can be found in use as a part of any research project focused on gene editing. After the regular

[27] Although Doudna has largely become the public face associated with the development of CRISPR technology, there has been a lengthy patent battle taking between UC-Berkeley (Doudna's home institution) and the Broad Institute at MIT as to who should actually own the CRISPR patent.

laboratory use of Cas9 exploded around the world, and the potential for its someday clinical use an almost certainty, Doudna took to the public stage and called for global conversations about the societal and ethical implications of using this technology on humans. In a September 2015 TED talk, she addressed the need to have conversations about the risk of clinically using the CRISPR-Cas system technology to alter human DNA.

> This raises a number of ethical questions that we have to carefully consider, and this is why I and my colleagues have called for a global pause in any clinical application of the CRISPR technology in human embryos, to give us time to really consider all the implications of doing so. And actually there is an important precedent for such a pause from the 1970s, when scientists got together to call for a moratorium on the use of molecular cloning, until the safety of that technology could be tested carefully and validated. (Doudna, 2015)

What Doudna suggests in her call for pause and reflection comes only after the reality of using CRISPR-Cas technology outside of the laboratory has become a real possibility. Now she wants the biomedical community to consider the potential ethical implications of clinically using CRISPR. However, why did she and others in field fail to address this question before CRISPR became clinically viable? This question should have arisen earlier in the design process. Rather than first design a novel biomedical technology and then ask about its ethical implications, why not ask about the potential implications as the technology is designed? In other words, should the CRISPR-Cas system, which was always intended for the targeting and editing of genetic code, have been developed in the first place? Waiting until a technology is ready for clinical use may mean it is already too late to make changes to the technology and thereby avoid potential negative impacts.

Although CRISPR is used almost exclusively in a laboratory setting, it is regularly referred to as a technology by biomedical engineers. If the line between what is and what is not a technology is drawn at the laboratory wall, then how did CRISPR come to achieve that designation? Perhaps part of the reason is because the line between the laboratory and the clinic

is not the only factor weighed in determining when to affix the technology label. The CRISPR-Cas system became a technology not only for its likelihood of clinical application, but also because the scientific knowledge it contains became settled among the biomedical engineering community. It was settled not only in the way that the targeting and editing approach it uses was demonstrated to prove its effectiveness and efficiency, but also because the technology was granted a patent, which marks a closing point to the open frontier of developing the first novel gene-editing technology. This black-boxing of gene-editing knowledge closes a technological frontier, but it also results in the loss of knowledge among cellular biomedical engineers to understand exactly how to target and edit certain genetic codes.

The transparency of what goes into making gene editing possible is becoming—and, to some extent, has already become—increasingly opaque to cellular biomedical engineers. Until CRISPR was developed, biomedical engineers were expected to understand all of the intricacies of working with cellular protein engineering. The questions of how this was done, who had the most efficient approach, and what was the most effective were debated in the disciplinary literature (Gross, 2016). However, once CRISPR became widely available, the scientific knowledge inherent to its design was black-boxed from those who no longer had to learn it. In my interview with Nadia, she spoke about how researchers working with genetic engineering had to understand the fundamentals of how to hack the DNA of a cell before CRISPR's public debut.

> CRISPR came on the scene at the end of my Ph.D.…I didn't have this when doing my gene-editing research… I had to have a serious understanding of DNA recombination events, the nucleus, and all that stuff. Now, CRISPR is just a tool people use, and they don't really know what goes into it - it's boxed off.
>
> (Nadia, postdoc, visiting scholar, cell lab)

The next generation of cellular biomedical engineers will be trained without the same level of knowledge about the biological function that makes genetic targeting and editing possible, even though the principles and methods used in the pre-CRISPR era remain relevant

and useful (Urnov, 2019).

Cellular biomedical engineers, as designers of novel biomedical technologies, need to maintain transparency into physiological dynamics and the processes they manipulate. This is especially true for researchers working with genetics and biological complexity. Genes work in groups and systems, with each having a full range of interactions that are yet to be fully understood (Noble, 2008; Noble, 2016). The reality is that the potential risks associated with using genetic engineering are unknown, because one cannot entirely comprehend the role of genes within the larger physiological system. There is a safety risk associated with designing novel cellular biomedical technologies that reify genetic reductionism, and this risk increases when elements of those technologies are built using black-boxed knowledge about biological functionality. Cellular biomedical engineers must maintain transparency into the biological and physiological interactions of the human body to avoid the potentially negative ethical consequences that Doudna and other biomedical engineers like her say must be addressed before CRISPR is regularly used for clinical treatment.

5.2 Just a Scientist Living in an Engineer's World

The goals associated with early-stage (stage T0) laboratory activities often align with what it means to be a scientist versus an engineer, according to biomedical engineers in general. Cellular biomedical engineers especially feel the push and pull associated with claiming alliance with a scientist identity more so than with an engineering identity. This battle between identities suggests implications for what cellular biomedical engineers actually mean when they use terms such as technology and impact, as each has a different connotation depending on the laboratory context. Let us consider this point further by looking more closely at what it means for a cellular biomedical engineer to identify more as a scientist than as an engineer.

More than 75% of cellular biomedical engineers included in this study identified as

being a scientist rather than as an engineer, but only 16% of biomedical device engineers claimed that label.[28] How study participants described the qualities of each identity aligned with the differences highlighted in Pasteur's quadrant, with the described qualities of a scientist placing them in the "pure basic research" quadrant and the qualities of an engineer placing them in the "pure applied research" quadrant. The following qualities of a scientist were described by cellular biomedical engineers Takara and Zhao as:

> "Scientists want to understand things on a fundamental level."
> (Takara, Ph.D. student)

> "A scientist wants to answer a question versus solve a problem."
> (Zhao, Ph.D. student)

These descriptions reflect the type of basic scientific activities that cellular biomedical engineers, as scientists, perform in their laboratories. For some cellular biomedical engineers, however, their location within colleges of engineering appears to contribute to their desire to be more like engineers.[29] This sentiment was especially present when interviewing the following study participants.

> I think I'm a scientist who will forever be jealous of engineers. I trained as a scientist, but I'm drawn to engineering, partly because I've always just liked that in-use practicality of engineering, like their whole motivation is to build something.
> (Johnathon, postdoc, cell lab)

> I think I want to be an engineer, but I am naturally driven to be a scientist. I'm much more curious and I get distracted by basic phenomena, rather than pushing toward an outcome and a deliverable.
> (Vincent, PI, cell lab)

The association with an engineering identity aligns with developing practical tools and technology, a deliverable that goes out into the world. The desire for scientist-identified

[28] It should also be noted that the only biomedical device engineers who identified in part or in whole as being scientists were those who had or were earning an MD along with their Ph.D.
[29] This sentiment was not expressed by biomedical device engineers who identified as engineers. No one expressed a desire to be thought of as more of a scientist.

biomedical engineers to be like engineers demonstrates an internalized expectation shaped by the surrounding culture within the discipline. Their location within engineering-dominant environments instills a drive to prove themselves as engineers that results in the desire to produce something that has *impact*.

There is a difference between what a cellular biomedical engineer and a device biomedical engineer mean when they use the word "impact" to describe their technological design goals. As I observed biomedical engineers discuss laboratory projects during group meetings, I noticed that they often wanted to pursue certain avenues because doing so would have more impact. While I had originally assumed they were referring to patient impacts, I realized over time they were really talking about journal impact factors.

The difference between having an impact on the wellbeing of patients and having an impact on scientific knowledge is important to recognize. The manner in which the term "impact" is used in cellular biomedical engineering laboratories is really a proxy for journal impact factors. In an interview with Namita, a self-defined scientist, she expressed value for the impact of conducting basic scientific research.

> I respect people who really look at basic science stuff. Like looking at single proteins… they definitely make much more impact when you think about it… If you find out a single protein mutation and publish it, the whole line afterward is just propagating off of it… That's why, when you look at scientific journals, basic science journals always have higher impact factors, because it's cited more.
>
> (Namita, Ph.D. student, cell lab)

In another interview, which I conducted many months after the one with Namita, I spoke with a postdoc who was working in conjunction with a genomic institute and a biomedical engineering laboratory, and he confirmed my suspicions as to what impact meant among cellular biomedical engineers.

> It would be an interesting history investigation to start to see where we started using these words…when did the environment start to demand this of things…like the word

> *impact*. We use that a lot, I mean I don't, but my boss says it all the time, and I've since then started learning a little bit about what that is. And I think if we distill it down, it sounds like it might have something to do with the journal impact factor. And like, is that what we really mean?
>
> (Johnathon, postdoc, cell lab)

Johnathon poses a critical values question when he asks if the use of the word "impact" by cellular biomedical engineers really does mean journal impact factor versus patient healthcare impact. Why has the meaning of this term become so ambiguous in cellular biomedical engineering laboratories?

Part of this ambiguity stems from the fact that cellular biomedical engineering laboratories are physically removed from various healthcare settings. This distance provides cellular biomedical engineers little opportunity to reflect on how their R&D activities will one day result in clinical impacts. Another part is that cellular biomedical engineers have little opportunity to closely collaborate with physicians on their stage T0 research projects. Recruiting clinical partners can be difficult for laboratories developing preclinical technologies. This is especially true for biomedical engineering laboratories embedded in universities that lack a medical campus or an affiliated hospital system. One cellular biomedical engineering laboratory PI spoke about the difficulties she experienced when attempting to recruit collaborators from a nearby non-university hospital.

> [T]hey're clinicians first, so research is not even in there, they're not thinking about doing it. They don't care about doing it, they don't know how to do it even if they want to do it. Clinicians at [name of hospital] are expected to see patients and make money. And so even if they wanted to be involved in research, a lot of times they can't. And then there's plenty of them that just don't want to, they're just like, "I'm here to make money, I'm going to go home and I don't care."
>
> (Sarafina, PI, cell lab)

Some of the cellular biomedical engineers I spoke with and observed wanted to have clinical collaborators for the same reasons as Sarafina. Their laboratory had a promising idea for a technology, or a part of a technology already in development, and wanted clinical input on how

to align it to a specific healthcare need. One of these laboratories, the Tango Lab, did have a clinical collaborator, but this group was in a different region of the country. The PI would travel twice a year to meet with this group, and they had virtual meetings once or twice more in the same year.

This collaboration fulfilled at least two goals for the Tango Lab. First, having a clinical co-PI on NIH grant applications helped to provide a competitive edge for funding. For example, in the case of the NIH, the agency introduced a new multiple-PI funding model in 2006 (NIH, 2019b).[30] The purpose of the multiple-PI program, according to the organization, is to address limitations of the RO1 program, which "does not always work well for multidisciplinary efforts and collaboration… increasingly, health-related research involves teams that vary in terms of size, hierarchy, location of participants, goals, disciplines, and structure" (NIH, 2019b). This was a change was based on feedback the NIH received from the 2003 Roadmap Initiative internal working group,[31] and was affirmed by a 2007 directive from the Office of Science and Technology Policy.[32] Encouraging multiple PIs to apply for a single grant communicates to researchers that the NIH values multidisciplinarity in its funded research projects. To increase application competitiveness, and therefore demonstrate alignment with the NIH's values, cell-based biomedical engineering laboratories may seek out clinical co-PIs.

The second reason a cellular biomedical engineering laboratory such as the Tango Lab might seek a clinical collaborator is to fill a knowledge gap concerning what happens between

[30] The new model did not replace the traditional RO1 grant program but works as a supplement to that program. However, with the introduction of the multiple-PI research project grant, the number of solo-PI RO1 grant applications dropped from approximately 80% in the late 1980s, compared to only 10% of RO1 applications listing a solo-PI.

[31] The NIH Roadmap Initiative working group helped to establish the current roadmap of translational medicine which models five-stages of biomedical research activities.

[32] The OSTP is a U.S. governmental office affiliated with the White House that was established in 1976 by Congress. The purpose of the office is to provide the Executive with advice related to the scientific, engineering, and technological aspects of the economy (OSTP, 2020).

academia and industry. For instance, the PI of the Tango Lab often emphasized to the group, and to me in our one-on-one conversations, that the real challenge of getting novel biomedical technologies into the clinic is not a deficiency in a laboratory's scientific knowledge but a lag in the technological progression from proof of concept to feasible product. In other words, there is a disconnect between the development of novel biomedical technologies in university-based laboratories and what companies believe they can manufacture and successfully sell on the market. Working with clinicians provides insight into this development gap between academia and industry. Cellular biomedical engineers, in turn, learn how to design their novel technologies in ways that better translate into products that companies will want to manufacture and sell to healthcare providers.

5.2.1 Intellectual Property and Technology Transfer

One of the explicit design goals for some cell-based laboratory PIs is to develop a product for which the associated intellectual property (IP) is eligible for patent protection. One of the important features of obtaining a patent is that it makes the IP available for licensing by companies that then upscale the manufacturing and commercially sell the technology. Key to the IP transfer process is the establishment of a start-up company by a laboratory member.[33] Creating a start-up has become an indicator of perceived success in the biomedical engineering community. One study participant reflected on recent faculty hires in his department and said that every new hire in the past five to six years came to the university with an already established start-up. In an interview with Aaron, whose laboratory was in the process of developing a nanosized drug delivery platform, he spoke of his PI's desire to establish such a company.

[33] Usually the person who leads to the charge to establish a start-up in the laboratory PI However, increasingly biomedical engineering doctoral students attempt to create start-ups before graduating. In this study, 20% of doctoral students working in cellular biomedical engineering laboratories had established, or were in the process of establishing, a start-up company.

> [B]asically, the final part of this drug development process will be funded by a pharmaceutical company…so someone in academia will usually go out and make their little biotech start-up, and then a pharmaceutical company will go and buy that whole pipeline…like my PI, he's just like, "things move too slowly in academia"…like if you want to get something out as an actual product, you ultimately have to make a start-up company or whatever.
>
> (Aaron, junior Ph.D. student, cell lab)

Establishing a start-up might suggest to others in the biomedical engineering community that the researcher has the knowledge and tools necessary to move novel biomedical technologies closer to market. However, this belief is not supported by the statistics, which suggest that fewer than 5% of biomedical technology start-ups ever produce a product that makes it to market (Booth, 2019). So why is there a push within the biomedical engineering community for researchers to pursue start-ups as a research goal?

The emphasis on establishing start-up companies and seeking patent protections within biomedical engineering is due in part to the now-institutionalized initiatives inspired by the Bayh-Dole Act. The principles of the BDA, including support for the value of private property and a free-market economy, are now well espoused in biomedical engineering programs. Biomedical engineers are trained to embrace these principles and values from their earliest days of competing in company-sponsored undergraduate design competitions, to receiving industry-funded career awards, to accepting research grants provided by for-profit businesses. Unfortunately, the BDA also conflates the potential for the utility of technology with its ability to be marketed successfully and earn a profit. Universities demonstrate their support for the commercialization of laboratory developments by implementing technology transfer offices (TTOs) on campus.

TTOs work with university-based laboratories to help them through the steps of patenting novel research and establishing start-ups, and they also serve as a way to protect the university's IP and financial interests associated with the project. The cellular biomedical engineers included

in this study, however, tended to either strongly support or strongly disapprove of the presence of TTOs. For those who love them, such as Lorenzo, a PI of a synthetic biology laboratory, "Technology transfer offices are wonderful; they help with the whole process." Lorenzo was able to patent a few laboratory discoveries that were now routinely used by other researchers around the country. His positive view of TTOs was also shared by a postdoc who worked in a technology transfer office while earning her master's degree.

> I think tech transfer is a very necessary thing… If a professor comes up with something, or someone at the university comes up with something that could be commercializable… the tech transfer office will walk through all the steps to secure a patent if that's something that makes sense for the technology. Or sometimes they will spin out start-ups, or perhaps get the technology licensed to a different company, so they handle all that… It just makes sense for the university and professor to protect themselves.
>
> (Emily, postdoc, device lab)

For some cellular biomedical engineers, TTOs present a helpful resource to move innovations closer to market. They assist individuals trained in basic scientific activities with making inroads into the next stages of technological translation. In other words, they help bridge the technology utility gap between what it means to be a scientist versus an engineer.

However, not all cellular biomedical engineers included in this study expressed support for TTOs on university campuses. Before interviewing cellular biomedical engineers about this specific issue, my assumption was that those individuals I had observed make derogatory comments about TTOs did so because they held an allegiance to the ideal that scientific goods should be viewed as public goods. However, what I found was that cellular biomedical engineers who expressed a resistance to TTOs rarely did so along philosophical or ideological parameters. Their resistance came from experiences working with TTOs and encountering what one interviewee described as mismatched expectations. For instance, a PI of a cell-based laboratory implied that TTOs look for ways to deny help in receiving a patent, that "unless you cross every 't' and dot every 'i' in the perfect way," the process causes more problems than it solves. In an

interview with Arjun, a former technology transfer manager, he presented the following counter narrative based on his experience working with a cellular biomedical engineering laboratory developing a nanosized drug delivery system.

> Often it's the PIs themselves who are the ones sabotaging their own chances because they'll have already described either the exact thing that they disclose to the TTO, or something very similar two years ago at a poster conference….or it'll be just be on like the laboratory's website, not even realizing that they described it that way… Or commonly something will be in the discussion section at the end of a journal article and they'll hypothesize where this could go in the future, and then two years later they actually act on that like that imagined use, but they already described it in this discussion section.
>
> (Arjun, postdoc, device lab)

What is important to recognize from this debate is that technology transfer is not something resisted by cellular biomedical engineers on ideological grounds. Their frustrations with TTOs derive from not understanding how the process works and from the expectation for more financial payoff than is often realistic. This suggests that cellular biomedical engineers are aligned with the principles and values of technology transfer but are generally resistant to the office because it appears not to be doing a good job.

5.3 Deciphering the End User

The process of translating a novel cell-based technology to the clinic involves many actors before it is ready for patient use. The result is that cellular biomedical engineers do not consider the end user directly, as their view of the end user is mediated by the FDA and industry partners. The perceived end user may even become these nonpatient actors, since the expectation is that they will take over the production and commercialization of the technology itself. Consequently, the needs and wants of these intermediaries may take precedence over those of patients during the design process of cellular biomedical technologies. Then, the use of these technologies on patients may result in negative impacts because their diagnostic and treatment needs were not fully considered in the early design stages. This design approach also offers

cellular biomedical engineers the opportunity to deflect part of their responsibility to design safe novel cell-based technologies onto their intermediary nonpatient actors.

My assumption coming into this dissertation project was that patients would serve as the imagined and intended end user of novel cellular biotechnologies developed in the laboratory. However, based on my observations of and conversations with cellular biomedical engineers, this does not seem to be the case. Laboratories working at the early stages of translation contemplate how to make their novel technologies more attractive to potential industry partners. They want to find companies that will take over the development process once a successful proof of concept has been achieved. With preclinical technologies, companies want to see evidence that the FDA is likely to approve such technologies for sale on the market.

One FDA issue that cellular biomedical engineers contend with is the debate over classifying cell-based technologies as *devices* or as *medicines.* The distinction between these two categories is in constant flux, since so few cell-based technologies have been approved by the FDA (Golchin & Farahany, 2019). Many of the cellular biomedical engineers included in this study made reference to the CRISPR-Cas system when trying to categorize their novel technologies. CRISPR serves as a way to navigate this distinction, since it can be classified as either a device or a medicine depending on the context of use (Asquer & Krachkovskaya, 2020). The FDA has also approved CRISPR for a small handful of highly specific clinical uses.[34] Some pundits (Brennan, 2015; Henderson & Shankar, 2017) argue that it is a categorical mistake to classify such cell-based treatments as medicines.

Part of the argument against the classification of cell-based technologies as medicines is that it slows down the translational process. Cell and tissue definitions in general are more

[34] CRISPR technology is used in a handful of FDA approved gene therapies. One of the more publicly known treatments is called Luxturna which treats a defective gene known for causing a certain type of retinal dystrophy.

complex than devices, so they require new methodologies to assess their hazards and risks (Gardner & Webster, 2016). Those who wish to pursue a device designation for cell-based technologies do so because they do not want bureaucracy impeding the translational nature of these technologies. However, developing new methods to assess the risks and hazards of cell-based treatments as medicines seems like the route the FDA has so far decided to take, at least in the case of gene therapies. This debate will likely continue for some time, but until then, cellular biomedical engineers will need to determine on their own how to manage the yet-to-be-defined risks associated with the novel technologies they design.

As I observed a cellular biomedical engineer Ph.D. student perform an experiment using a certain type of nanocarrier, I asked her why she had chosen to use a particular type of material in her design. She told me the choice was made to use sugar nanocarriers because they are natural molecules in the body and added that her laboratory prioritized this type of material in its design because many similar innovations had already been approved for human use in other countries. The hope, therefore, was that if this material had been accepted in other countries, the FDA would be more likely to approve it for human use in the United States. Contemplating FDA approvals is one way in which cellular biomedical engineers implicitly insert consideration for human impacts into their design practices. Since the FDA is regarded as the body responsible for protecting human health through safety and efficacy regulations (FDA, 2018b), the unspoken assumption among cellular biomedical engineers is that the FDA will do that with novel cell-based technologies as well.

Technological design considerations among cellular biomedical engineers are filtered through a perspective that values what the FDA might be willing to approve further down the translational development pipeline. For instance, I observed multiple subgroup lab meetings in which members negotiated which materials they believed should be used as a part of their design

protocols. The primary reason one material might be chosen over another often came down to its potential to be biocompatible.[35] In one slightly frustrated exchange I observed between a lab PI and a postdoc, as the postdoc continued to highlight how bright his image was when using the 583-sized QD[36] in his experiments, the lab PI told him to stop using that size until "we can add someone to the group with the right polymer knowledge." This had not been the first time the postdoc had been told to stop using that sized QD. The postdoc liked this QD because it produced the brightest single-cell tracking image and generated positive data for publications, but the PI did not approve of it because its core material made it unsafe and less marketable. Adding a polymer layer to the QD makes it safer for physiological use, but that comes with the trade-off of likely decreasing the brightness of the cell image. Knowing that the PI ultimately wanted to receive a patent for this innovation and a license with a manufacturer, I knew his desire to wait for someone with polymer knowledge was motivated by the goal of improving the QD's attractiveness to potential industry partners. Although not explicitly regarded as such, these type of design considerations reflect a concern for human safety and security, albeit through the lens of what the FDA might be more likely to approve.

In many of the interviews I conducted with cellular biomedical engineers, I asked whether their laboratory ever considered the potential social impacts of the innovations they were developing. I was particularly interested to pose this question to anyone working with nanomaterials. These types of materials take on unique properties when designed at the nanoscale and enable biomedical engineers to create systems or devices with enhanced or completely new characteristics and properties (Kosky, et al., 2013). In an interview with a Ph.D.

[35] Where biocompatibility is defined as materials or nanotechnologies that when used do not result in physiological harm to the body (Gordijn, De Vries & O'Mathuna, 2011).
[36] Not the actual size of the QD discussed which is unique to this lab. The number was changed to protect the identity of this group.

student who had received all of her educational and laboratory training in nanotechnologies, I asked her if she had ever been part of a laboratory group where they explicitly talked about the potential social impacts that might result from the clinical use of any of the bionanotechnologies they were developing. She paused before answering and seemed unclear about what I meant when asking about social impacts.

> I don't think so (pause), I don't think we consider it in the projects. I mean (long pause), I guess we maybe consider more like medical outcomes…but not social outcomes…but really, that's because we hope to deliver this to like industry or to medical doctors, and you know, then they'll sort of see what they do with it.
>
> (Isabella, Ph.D. student, cell lab)

Isabella's answer initiated a bit of an "ah-ha" moment for me as I reflected on what her answer implied. Social impacts are not explicitly considered by cellular biomedical engineers because they primarily focus on how to achieve translation. These laboratory groups are primarily concerned with how to create innovations that are appealing to others who will take over the next stages of technological development.

Since none of the cellular biomedical engineers I interviewed indicated that patients served as their imagined end users, I began to wonder if clinicians might serve in this capacity. Specifically, if the stages of translation suggest that a novel cell-based technology starts in laboratory, then receives a patent, then is licensed by a company, which then conducts clinical trials to earn FDA approvals, the next step would be the sale of biomedical technologies to healthcare providers. Is it possible that clinicians might also, in some way, be perceived as the end user of a novel cellular biotechnology? In an interview with a Ph.D. student who referred to her laboratory developments as products and who strongly identified as a member of a translational laboratory, I asked whether she thought her group regarded clinicians as the end users of their products.

Um (pause), thinking about the end user clinically? I mean (pause), I guess there's

> always some basic knowledge that (pause), like if we're working with a different material like there's some learning and understanding that goes with that along the way, just because that's part of our process, but our focus is definitely in the translation.
>
> (Lamia, Ph.D. student, cell lab)

In my conversation with Lamia, she repeatedly emphasized how much her laboratory cared about translation. However, as we continued to discuss what that really meant to her and the laboratory, she implied that focusing on the translational aspect of the research meant her group did not need to consider clinical users outside of a materiality of the design perspective. In another interview with a Ph.D. student working in a different lab than Lamia, but with similar nanotechnologies as Isabella, I asked whether her laboratory saw medical doctors as the end users of the tools they were developing.

> I think it would have to go through a company first who would then have to develop it, and get the regulatory approvals, and market it before clinicians could get there. So I think it's definitely a long road from where the physician can be the end user (laughs).
>
> (Ying, Ph.D. student, cell lab)

Cellular biomedical engineers end up making implicit assumptions about who constitutes the likely end user of their novel technologies because the process of translation confounds who occupies that position. Since laboratories understand that the next immediate step in translation is the transfer of control to industry groups, cellular biomedical engineers may not adequately address clinical needs during the design process. If the imagined end user of what is developed in a cell-based laboratory is a company, or the FDA, the real-world health needs of humans may be overlooked. Novel cellular biotechnologies may inadvertently be designed in ways that risk unintended consequences when used to diagnose and treat patients.

Cellular biomedical engineering laboratories demonstrate a misaligned conceptualization of who constitutes the end user of these novel technologies. This results in the prioritization of design parameters that are more aligned with values in support of private property and commercialization versus the safeguarding of human wellbeing. This misalignment of what is

important during the design process demonstrates how value-based design interventions need to consider more than user-based consequences. Interventions must also consider how values within the laboratory influence how researchers direct their design practices. Cellular biomedical engineers are so far upstream from the actual real-world deployment of their technologies that the benefit of contemplating only use-based consequences at this stage is limited. Interventions are needed that focus on the role and duties of what it means to be an upstream designer of novel cellular biomedical technologies.

CHAPTER 6: BIOMEDICAL DEVICE ENGINEERS

The research and development (R&D) activities of biomedical device engineering laboratories differ from their cellular biomedical engineering counterparts in several ways. These differences largely stem from where along the translational roadmap each group begins its technological design projects. Biomedical device engineers, as downstream researchers, arguably have more opportunities to interact with physicians and patients than do cellular biomedical engineers. However, exposure alone is not enough to guarantee that laboratory design practices will result in the use of novel biomedical device technologies that properly safeguard human wellbeing. Biomedical device engineers have the responsibility to develop novel hardware and software applications but to do so with the expectation that such applications will seamlessly integrate with existing technologies. These technologies, referred to here as post-translational technologies, have core elements that have already received certain FDA approvals and are regularly used within clinical settings. While working with post-translational technologies should provide biomedical device engineers the necessary information to avoid negative impacts of using novel technologies, unlike cellular biomedical engineers, they do not have the power to make changes to core devices that are well-entrenched for use within the clinic.

Biomedical device engineering laboratories and cellular biomedical engineering laboratories do share a particularly concerning attribute, but the origin differs by group. Both groups of biomedical engineers engage in laboratory practices that instill distance between themselves and the healthcare realities of both physicians and patients. Where cellular biomedical engineers are located upstream in the translational process and are thereby epistemologically removed from the clinical context in which to situate their technological developments, biomedical device engineers engage in laboratory activities that black-box physiological processes and turn them into abstract representations. These design practices

suggest values implications for the future use of novel biomedical device technologies.

This chapter argues that the laboratory R&D activities of biomedical device engineers evince implications for the values of responsibility and transparency. Biomedical device engineers acknowledge working with device technologies, but as they make changes to these devices, researchers assume they remain safe for clinical use. This assumption minimizes their perceived responsibility to assess the continued safety of the devices. Additionally, the laboratory activities of biomedical device engineers systematically obscure biological complexity. This decreases the amount of transparency into these functions that are critical for designing safe systems. This argument is presented in the following three sections.

First, biomedical device engineers think of themselves as users of technology instead of creators of technology. Their mission is seen as one where the goal is to improve or optimize a biomedical device that is already in use in clinical settings. Working with post-translational technologies instills in biomedical device engineers the questionable belief that core devices remain safe for human use even when integrated with novel applications. Biomedical device engineers also express sentiments that suggest they do not consider themselves as the actors responsible for making changes to the core elements of a post-translational technology. Such a perspective limits their capacity to acknowledge that they also have a level of responsibility to engage in technological design practices that safeguard human wellbeing.

Second, biomedical device engineers work extensively with data and software code. The research activities associated with types of projects suggest two ways in which the value of transparency is implicated. The first is that some biomedical device engineers want to protect the originality, and the potential patentability, of their code and are hesitant to share the core freely with other researchers. This limits the access that others have to this scientific knowledge and may delay developing biomedical technologies that improve human health. The second

implication connects to the relationship that biomedical device engineering laboratories have with industry partners. These partnerships often result in companies providing funds to laboratories and the expectation of a proprietary right to the data and applications developed. This is another way in which data and code are shielded from other researchers in the field and that limits transparency into the development process of novel biomedical devices.

Lastly, there is an epistemological tension between the value that biomedical device engineers place on engineering and mathematics over biology. This knowledge hierarchy is used to justify laboratory practices that convert complex biological processes into abstract representations. These practices include efforts to increase the quantification of biology and the use of biological simulation software. Unfortunately, such activities also minimize the amount of transparency that researchers maintain in dynamic physiological interactions. This lack of continued transparency implicates the design of novel biomedical devices and potentially risks patient safety when they are treated with these technologies in the future.

6.1 Post-Translational Technology: Fixed or Evolving?

Biomedical device engineers are quick to acknowledge that they do, in fact, work with technology. Unlike cellular biomedical engineers, who resist the technology label to describe their laboratory developments, biomedical device engineers know they interact with technology. The types of technologies that biomedical device engineers develop actually establish the standard for what all biomedical engineers envision as they attempt to determine what constitutes an actual biomedical technology. For example, in an interview with a cellular biomedical engineer who was in the process of designing synthetic tissue, he used (unprompted) the very biomedical devices under discussion in this study to demonstrate how his research is not about technology.

[B]ecause when I think of technology, I think of very concrete kind of things. You know,

> like your rehabilitation people with prosthetics and stuff, or a new device or imaging… how I've heard the word…been accustomed to it, I wouldn't say I work on technology. (Seon, Ph.D. student, cell lab)

The core device of an ultrasound machine, a prosthetic, or an MRI machine represents the default idea of what biomedical technologies actually *are* (in terms of being) within biomedical engineering communities. They are what Seon refers to as *concrete* in terms of their actual manifestation and their use with people.

There is an implicit recognition within this notion of the concrete that speaks to the belief in the biomedical engineering community that, for something to be classified as a technology, it must demonstrate some level of utility. Biomedical device engineers call attention to this utility when they contextualize their research activities as working with *clinical* technology. Adding this qualifier to the term technology, which I refer to here as a post-translational technology, serves as a reminder that the technology in question has already made the successful transition from the laboratory to the clinic. Since device technologies such as MRIs, ultrasound, and prosthetics are already used to treat patients, they demonstrate their clinical utility, which is highly valued among biomedical engineers.

This value for clinical utility is, undoubtedly, a positive factor and contributes to the overall well-being of people. However, once the label of clinical is assigned to a biomedical technology, it instills a false sense of security that any future optimizations or improvements made to the technology mean it remains just as safe and secure for continued human use. For example, in my conversations with biomedical device engineers, I would ask if they ever thought about potential negative impacts of their research. This question was often met with stares, and respondents would attempt to clarify by asking, "You mean safety stuff?" I would then respond, "Yeah, sure, just anything about how it could be potentially harmful?" Participants would then shake their heads no, and three biomedical device engineers answered:

Participant No. 1: You mean with like the MRI itself? There's no need for that, like MRI already exists.
Participant No. 2: Well…medically this helps with determining tissue stiffness. That doesn't hurt people, it helps people.
Participant No. 3: No, no, all of this is safe. It was tested like years and years ago and we wouldn't use it if was harmful.

The idea that an optimized or improved device is, in any way, a new device,[37] which would require additional or renewed safety tests, was not the position of any biomedical device engineers included in this study. The core devices at the center of these research projects appear to be considered settled technologies by the researchers; in other words, once a device is post-translational, any version of it thereafter remains safe for continued human use. For example, Participant No. 1 suggests that MRI machines are safe because they already exist. However, this biomedical device engineer is developing a new type of coil for the machine that would fix certain types of abnormal magnetic fields. How does one know that the use of this new coil will not change the magnetic fields in ways that are potentially harmful to the patient? Additionally, why are biomedical device engineers not encouraged to engage in this type of reflection regarding the continued safety of these altered technologies?

Some answers to these questions can be found by examining how biomedical device engineers describe their relationship with device technologies. The overall depiction suggests a distancing between themselves as responsible actors in the creation of technology. Biomedical device engineers are reluctant to identify themselves as researchers who are responsible for creating technology; they prefer to be thought of as users of technology. For example, during an interview with a biomedical device engineer working with both ultrasound and MRI, Jie highlights the distinction between what it means to be a maker of a technology versus a user of a

[37] In terms of how any time a technology is altered it is new in respect to that configuration has never existed before; therefore, could result in different results when interacting with a human body.

technology.

> [W]e're not so much making technologies, we are trying to produce something useful, to advance the technology. So I'm using the technology, all the data, and all the things we have right now is thanks to the current technology. If we didn't have these machines we couldn't come up with these fancy data and improve the image resolution.
>
> (Jie, Ph.D. student, device lab)

This distinction between using a technology versus creating a technology indicates that biomedical device engineers consider themselves more as people who interact with technology instead of create technology. They seek to make technology better, in terms of functionality as well as patient treatment (which, from a values perspective, is a positive goal), but their self-identification as users of the very technologies they help to create suggests there is a power problem at play in biomedical device engineering laboratories.

With the Collingridge dilemma (Collingridge, 1980) comes the double-bind problem suggesting that, at some point in the technology design process, developers face a power problem that limits their efforts to influence or control the continued development of a technology. This problem is that having the ability to change a technology decreases once its use has become socially entrenched. One biomedical device engineer participant, Stefania, said she believed that improved MRIs do remain safe for patient use in general, but she also spoke about the negative psychological impact some patients feel when using a standard MRI machine. This participant spoke about her experience working with human subject volunteers, witnessing them feel claustrophobic when entering the narrow tube of an MRI machine. Stefania commented, "Why can't we make the opening bigger? There is no reason it can't be for the technique I'm developing." If Stefania and other biomedical device engineers like her are, in fact, the creators of these novel technologies, then why can they not make this type of adjustment to the core device? This is especially important, since a change such as this one, which would not alter the diagnostic functionality of the device, would result in improved overall human wellbeing.

The reality is that it is difficult to change a post-translational technology because more actors are involved at this point who also have some level of responsibility for and influence over how a device continues to be produced. When I asked Stefania whether her laboratory group could make changes to the size of the MRI opening, she laughed and said there was no way the manufacturer would allow such an alteration: It would cost too much and take too long to implement. The power problem experienced by biomedical device engineers who work with post-translational technologies demonstrates how the entrenchment of a technology is only one reason it becomes difficult to change after it has been socially adopted. The more that additional actors are involved in the manufacture, production, and sales of biomedical devices, the more power and control that biomedical device engineers lose to make technological design changes to improve the overall experience for patients.

6.2 Data Models, Software, and Intellectual Property Issues

One type of common research activity found in biomedical device engineering laboratories is the building of data models that are then either used for clinical diagnostics or for patient treatment purposes. A process of abstraction takes place as biomedical device engineers construct these models, and this process works to simplify the otherwise messy and unpredictable activities associated with physiological function. The translation of muscle movements into mathematical expressions, for example, gives biomedical device engineers a tangible tool that they can then use to fully control and manipulate biological information. Biomedical device engineers move on to directly engage with data models instead of with patients and, in such a way, they avoid the unknowns associated with human physiology. This act of distancing oneself from the complexity of biology also shifts the focus of the biomedical device engineer away from the values implications of the device.

6.2.1 Building Data Models

A rapidly evolving area in novel biomedical device engineering is the development of algorithmic models that are built from recording and measuring neural pathways and neural modulation (Hench, Jones & Fenn, 2012). The resultant models are then integrated with prosthetic devices so their movements become more smooth or "natural"-looking and so patients can receive neural implants that help them move limb prosthetics based on neural impulses (i.e., by thought). Biomedical device engineers who use either invasive or noninvasive electrodes to collect brain data spend significant amounts of time building these models for next-generation prosthetics. For example, William, a doctoral student in an upper-limb biomedical device engineering laboratory, spends most of his days working with test subjects in the movement lab to collect data.

> It's called electromyography (EMG); it's basically just measuring the electrical activity of the muscles while you're using them, and with this project it's with electrodes on the surface of the skin. There's different kinds, there's invasive ones, but I use surface, and I'm using what's called a high-density EMG, which is basically just a ton of electrodes together in a grid that give you more information. I'm having people extend each of their fingers in different variations of force levels, and while I'm (doing so) I'm measuring that EMG signal and then I'm going back after the fact and trying to see if we can use that EMG signal to predict what force level the output is, and then it's in the model we use.
>
> (William, Ph.D. student, device lab)

William proceeded to give me a tour of his laboratory and pointed out the various prosthetic arms in development to work in conjunction with the neural data model he was creating. He demonstrated to me how having a better understanding of how and where fingers emit force as they move helps him and his laboratory group build better interfaces for use with prosthetics devices.

The interface that William's laboratory is building is what makes its biomedical technology novel, but the data model on which it relies is not entirely new. The purpose of William's research is to make this neurological model more accurate and efficient in reading and

interpreting the data it receives. Key to this process is the writing and building of mathematical algorithms that represent biological and physiological processes in a simplified format. Biomedical device engineering laboratories build such models not only to interpret neurological functions but also to interact with any type of physical process that this particular device is designed to capture.

Many biomedical device engineers working with MRI machines construct algorithms with the explicit goal of improving the image detection and signal processing when collecting data bits of information from human body scans. For example, such a project served at the center of an MRI imaging project that Sumon and his laboratory group completed recently. He spoke to me about what made this technology novel within the context of MRI machines.

> So the process we developed…it pretty much reduces the imaging scan time of elastography studies by two-thirds. So basically, if a scan would take 60 minutes, our imaging scan would take 20 minutes because of the new concept that was developed. So we were able to get a patent out of that.
>
> (Sumon, Ph.D. student, device lab)

There are two important values drivers suggested in Sumon's statement. The first is that the laboratory had the explicit intent to develop a technology that would decrease the amount of time physicians and patients must wait for MRI test results. This demonstrates a value for improved patient wellbeing by reducing the time needed to receive results and by limiting the time a person must spend inside an MRI machine to be scanned. The second value driver is the push to develop a type of technological novelty that would result in receipt of a patent. The foundational concept behind this new processing technique ultimately did receive a patent, which the PI shared with members of his laboratory. When I asked Sumon if anyone was now working with manufacturers or physicians to support this process moving forward into clinical treatment plans, he smiled at me and replied, "Oh no; someone will take this and do something with it. We're now using the patent to help us apply for a grant for the next project." I return to the

connection between patents and grants later in the next subsection.

6.2.2 Intellectual Property and Patents

The desire to obtain a patent is a complicated issue among the biomedical device engineers included in this study. Some individuals believe it is important to pursue a patent to protect the intellectual property coming out of the laboratory. Others believe the knowledge produced in scientific environments should be made freely available to anyone. The issue of patents in this context highlights the values tensions that exist in biomedical engineering between the ideologies represented in the open science movement and those found in neoliberal policies. In other words, there is a tension between those individuals who believe scientific knowledge should be made transparent and accessible to all members of society versus individuals who endorse a market-driven approach that supports the privatization of intellectual property (e.g., patents).

Exploring the inherent complexity of this tension in biomedical device engineering requires examining how the values and objectives of multiple actors intersect with the topics of scientific knowledge, intellectual property, and patents. There are the biomedical device laboratories themselves, which are led by PIs but are also composed of many other individuals. These individuals may or may not disagree about the reason(s) why or why they should not pursue a patent. For example, in my interview with Natasha, a Ph.D. student who expressed a strong desire to pursue biomedical device sales after earning her doctorate, she told me how she was astonished upon learning that her PI did not want to patent the novel software coming out of his laboratory.

> I had approached my PI, because the simulation tools he developed are just amazing, and at some point I asked him if he was ever interested in commercializing or patenting those tools, because they would be very useful in the ultrasound research world. But basically he said no, if anyone wants it, I'll just give it to them for free; it's knowledge. (Natasha and Beth laugh.) I know! I mean, like I'm a regular normal Ph.D. student, I'm more

> passionate about commercializing, but that's just me, because I want an end goal…we need to sell it, we need to promote it. But I'm not traditionally in it for the science, and the academic value, which is what my PI is all about…he is pure science and knowledge to everyone.
>
> (Natasha, Ph.D. student, device lab)

The PI of this ultrasound laboratory expressed a value often associated with an open science perspective, that scientific knowledge is free knowledge and should be made available to others. During my conversation with Natasha, she clearly demonstrated a strong alignment with the goals of a free market that works toward the commercialization of both knowledge and products. Natasha also associated her support of these values with her identity as a Ph.D. student, and that, as a "normal" Ph.D. student, she wanted to pursue commercialization as an end goal.

The notion that a "normal" biomedical device engineer at any stage of their career should value private-property protections and commercial gain stands in contrast to the Mertonian norms of communalism and disinterestedness. These values oppose Merton, who suggested that researchers should have common ownership of scientific goods (including knowledge) and that collaboration and transparency is crucial to good science. Merton also believed that scientific institutions (such as university laboratories) should work together for the greater scientific enterprise rather than for personal gain. Although Natasha's values diverge from these Mertonian norms, the apparent values of her laboratory PI seem to echo these norms. How can such divergent viewpoints exist in the same laboratory?

Biomedical device engineers who are further along in their academic career, specifically, those who have achieved tenure, have the luxury of choosing to adopt the norms of communalism and disinterestedness and the values for common goods and free scientific knowledge. In my interview with Kurt, a full professor and the PI of a well-funded and highly published MRI laboratory, he shared with me that, as junior faculty member, he was afraid his best ideas (i.e., software code) would be taken by others if he shared them too much.

> I think when I was assistant professor, I was a little bit worried about, you know, getting scooped on things and sharing things out too broadly…if your research is really novel and you're the only thing out there, or there's only 10 things out there, then there's a lot of people looking at your code.
>
> (Kurt, PI, device lab)

Kurt continued by saying that, now that he has tenure, he is much less worried about openly sharing his code with other researchers. Part of this was based on the feeling that he needed to establish his originality in the field, and this meant confining the use of his code to the laboratory while he pursued patents. For Kurt, the desire to receive a patent was motivated not by commercial intent, because, as he said to me, "Nobody has ever told me how I'm supposed to make money off of any of these things anyway, so that's probably a good thing." Instead, Kurt wanted to obtain patents because he knew that having them would assist him in successfully seeking grants for his research.

Therefore, the desire to commercialize laboratory goods and knowledge is not the primary motivator behind why some biomedical device engineers seek patents for their work. When interview participants were asked why members of their laboratory might want to seek a patent, answers fell along two lines of thinking, as exemplified in the following quotes provided by two biomedical device engineering Ph.D. students.

> **Participant No. 1:** When we design things and start thinking about applications, what we can do to patent things out, we're thinking what can they do to take it out to society…
> **Participant No. 2:** This is the main goal of and the objective of all the grants…get the patents and you get the grants…

Implicit and explicit values are suggested in these quotes, and I address each in turn. The first statement conveys that the desire to receive a patent might not equate to the desire for commercial gain, but it still correlates with the notion that scientific knowledge is intellectual property that is patented. The implied association here suggests that receiving a patent means this knowledge can be used by others who then license it (via the patent) and who then apply it to

address some sort of societal health need. The tacit belief is that a patent is necessary before knowledge can be used for a practical application. The explicit value behind the first participant's statement is based on the desire to see this knowledge provide benefit to society, while the implicit value suggests that scientific knowledge is property that should be legally protected.

Although the notion of and value for private property may be hinted at by some biomedical device engineers, others are more direct in their support for researchers' decisions to pursue patents. In my interview with Camila, she speaks to the motivation for why someone might want to receive a patent for their work.

> [W]hether we get a patent or not is kind of an afterthought…I mean, you obviously want to protect your research, so that's why getting a patent is important, because it's a new technique no else has developed, but the first goal is to address grand challenges in the field. I mean, if something good comes out of that then you would be wise to protect that.
>
> (Camila, Ph.D. student, device lab)

The notion that researchers should make sure to "protect" their research demonstrates a belief that scientific outputs are thought of as private property. The value that Camila assigns to patents is that they maintain the ownership a researcher should have over the novel aspects of their research. Camila is only a first-year doctoral student but she has already begun to internalize the expectation found in the field of biomedical engineering that researchers should value the pursuit of patents as a part of their laboratory activities.

The other rationale behind pursuing a patent for research outputs is expressed in the second statement above about why members of a biomedical device engineering laboratory might want to receive a patent. Researchers who obtain patents are regarded as more competitive in their quest to receive grants to support their work. Patents send a signal to external funders that, as one biomedical device engineering postdoc stated, "tells them that you know what you're doing and you won't waste their money." Laboratories that hold patents also suggest to others

that the work taking place in those spaces is novel, the achievements of which hint at the potential for commercial gain to those who might partner with the laboratory, which, depending on the goals of the funder, may be particularly attractive.

The inclusion of patents in the laboratory activities of biomedical device engineers also introduces the values and objectives of additional actors into the patent-receipt calculus. Some actors, such as universities, already have a stake in the research outputs of biomedical device engineers, but patents add a new element. For example, for Sumon's laboratory, the patent it received for the novel image-scanning application is also held by the university, because universities are able to claim property rights of any intellectual property generated by faculty in the course of their employment (Amos & Miller, 2017). The passing of the Bayh-Dole Act by Congress in 1980 also ensured that universities could retain and profit from these patents. Should the patented technology emerging from Sumon's laboratory ultimately be licensed for use by a company, the university will be entitled to portions of any resultant profits given its ownership status.

The university has the potential to financially benefit from any patents received on behalf of the researchers it employs. This had led, in part, to the decision to introduce TTOs on university campuses and to provide start-to-finish services to establish start-up companies and file provisional patents in coordination with university researchers. Universities clearly value patents and increasingly are instituting programs and initiatives to support patent-related activities. Although statistics vary widely based on the type and complexity of technology under consideration, the average cost of a U.S. patent for biomedical technologies is approximately $20,000 (Farre-Mensa, 2019). Should a novel biomedical technology demonstrate outstanding potential for commercialization, the TTO will likely cover all of these fees, thereby again demonstrating its strong desire to promote among researchers the message that they should want

to pursue patents for their innovations.

Other likely vested actors in the patent scenario are commercial entities. Either directly or indirectly, their goals and wants are considered as biomedical device engineers contemplate patenting a novel technology. For example, in Kurt's laboratory, he had received funding from a commercial entity to develop a specific MRI hardware/software combination that the company wants to use in its next-generation MRI machines.[38] Because of his desire to keep aspects of this data-related information private, and thereby patent-eligible, Kurt had to adopt these values (i.e., of scientific knowledge as private property, for instance) as part of his project's objectives. However, Kurt is also a faculty member at a publicly funded university and a member of a laboratory that also receives funds from the NIH. How do the goals and values of these governmental actors intersect with those of the commercial entities involved in biomedical device engineering projects?

There is a general sense among biomedical device engineers that government funding agencies, such as the NIH, will soon require that researchers share part (or all) of their code with others. In 2017, the NIH approved a $2.45 million stage 1 application to pilot an open-source data-sharing repository (Nosek, et al., 2017). The purpose of the pilot is to coordinate and test *An Open, FAIRified Data Commons* with the intent to support "stakeholders who need access to scholarly process, content, and outcomes in pursuit of knowledge" (pg. 5). Kurt referred to this likely mandate from the NIH in an almost resigned tone, and told me that most companies already make part of the software code they fund available to other academic researchers who agree to sign an agreement limiting how they will use the information. However, this does not fully address the free access to knowledge values explicitly targeted as part of the NIH mandate.

[38] The specific company name and project details were asked be kept confidential by the interview participant.

Although there appears to be a general acceptance among biomedical device engineers that this change in the NIH's policy will happen, the real tension seems likely between industry funders of university research and the NIH. This results in an important question: What are the implications to industry ownership of intellectual property within the context of NIH data-sharing mandates? It will be important for values and design scholars to monitor this evolving issue in future studies.

6.3 Disciplinary Tensions

Similar to how the development of data models and software applications works to remove biomedical device engineers from the messy reality of physiological functions, the overall values and norms found in the (inter)discipline of biomedical engineering operates to enable and support this type of distancing. Biomedical engineering researchers and other stakeholders perceive a hierarchy between engineering and biology where the former is valued more than the latter. In effect, this hierarchy results in biomedical device engineering laboratory practices that tacitly devalue physiological processes. The internalization of the values associated with this hierarchy are reflected in many ways, starting with differences that biomedical engineers see between what it means to identify as an engineer versus as a scientist. Where cellular biomedical engineers mostly identified as scientists, with a desire to become or to be seen as engineers, more than 80% of the biomedical device engineers interviewed (regardless of career stage) identified solely as engineers.

Two primary characteristics are associated with what it means to be an engineer that have implications for the valuing of biological knowledge. The first is that the research goal of an engineer should be the development of a technology that is built for some type of explicit utility, that laboratory research activities should focus on creating a technology for a specific use. This viewpoint was expressed clearly by Arjun when drawing the distinction between what makes

someone a scientist versus an engineer.

> [W]hen I think of a scientist, I think of it as a pure pursuit of knowledge for knowledge's sake…there are reasons they're pursuing certain things, but with engineering I feel like it's all more focused. And there's this focus on creating a device for a specific reason.
> (Arjun, postdoc, device lab)

The implicit assumption here is that laboratory research focused on the pure pursuit of knowledge is not working toward the development of a technology with a specific application in mind. Those who do engage in laboratory practices with the goal of designing a technology for a specific reason are performing as engineers should. The question here is: What if a biomedical device engineer lacks the scientific knowledge needed to make their device ready for use? How do they design a device for a specific physiological application when biological processes are so complex and variable?

The answers to these questions are found when examining the second characteristic often associated with what it means to be an engineer. This suggests that someone who claims the engineer identity is a problem-solver motivated by the goal of making a technology work. This attribute was often used by interview participants to highlight the difference between what makes someone more of an engineer than a scientist.

> For engineering it's to solve the problem, and for scientists it's to gain more knowledge. Engineers look at a situation and think, what is wrong? Where can I fix it?
> (Parth, Ph.D. student, device lab)

> I feel like engineers are more driven by a problem that they see, more than curiosity.
> (Margaret, postdoc, device lab)

Scientists are regarded as researchers who follow a certain trail to see where it leads and to determine what type of knowledge can be gained, the assumption of which is that such laboratory activities are unconcerned with creating a technology and will simply follow a path wherever it goes. This characteristic is compared to the laboratory practices of engineers who are believed to focus on the technology itself and do not become distracted from the goal of

designing a technology ready for use.

Multiple study participants referred to the research done by scientists as "working in the weeds" and that viewing the world from this perspective means you do not "see the big picture," which is the domain of engineers. One first-year Ph.D. biomedical device engineering student touched on these issues as he described his decision to join a device-focused laboratory as a graduate student although his undergraduate training was in a cell-based laboratory.

> I don't want to be involved so far in the weeds such that maybe I'm investigating, for example, one particular gene and how it activates a protein. Where even if you're successful and you find something really novel, it might take 20, 25, 30 years, or whatever amount of time for that to really turn into something that's going to help people.
>
> (Dhruv, Ph.D. student, device lab)

Dhruv's desire to work in a device-based laboratory is seemingly motivated by the impetus to move technological solutions to the clinic faster so they can help people. This is a positive motivation within itself and does supports the value of upholding human wellbeing. However, within the context of translational medicine, where the most important goal is achieving clinical utility, the concern presented here is: How much does the goal of achieving clinical *utility* in a biomedical device engineering laboratory supersede the obtainment of *scientific knowledge* for the field?

A type of research design calculus takes place within biomedical device engineering laboratories when deciding whether pursuing scientific knowledge or achieving clinical utility should serve as the laboratory's primary goal. When biomedical device engineers are aware of the actual clinical use of the novel applications they develop, it becomes easier for them to determine when there might be no point in exploring something unknown on one side if the technology on the other side is not yet ready for it. The risk associated with this type of calculus is that developing the necessary scientific knowledge, specifically the necessary biological knowledge, will be minimized to solve for the technological "problem" faster. Again, this works

to move the biomedical device engineer even further away from dealing with the messy reality of physiological complexity.

6.3.1 Epistemological Underpinnings

There are times when the value hierarchy between engineering and biology is more explicitly acknowledged among biomedical engineers. Those who openly recognize this division tend to be more senior researchers in the field, and are quick to assert where in the hierarchy their research falls. Either they view their research as higher in the hierarchy, as engineering- and problem-solving focused, or they are aware that others regard their research activities as less important, as is the case for those working with biology and hypothesis-based projects. This hierarchy enforces a division between two camps (device-based and cell-based) of biomedical engineering, and also reflects the deeper epistemological divide that exists between these two fields of knowledge. This tension must be openly confronted to address the potential values implications.

In the early stages of this project, I attended my first conference of the Biomedical Engineering Society (BMES). One highly attended event at the conference was the award ceremony for professional achievements. One of the speakers, a well-respected tenured faculty member in the field, proceeded to introduce one of the awards, and off-handedly made the comment, “And like we all know, it’s easier to teach an engineer biology than it is to teach a biologist engineering.” This comment really stood out to me (but seemingly not to others), and over the next few months of my project, I began to see connections with what this suggests from a values perspective.

In one of my first interviews, I spoke with a laboratory PI who described her cell-based research as “fringe” to the larger discipline of biomedical engineering. She argued that there is a tension between individuals who represent the “old guard” of engineering within biomedical

engineering and individuals who represent the "new guard" of biology in the field.

> I think there are a lot of people, a lot of biomedical engineers, (for whom) the *bio* is part of their engineering. To me there's a divide; there's engineering *of* biology, which is what I do with cells and proteins, and then there's engineering *for* biology, which is devices, and, you know, algorithms for imaging.
>
> (Sarafina, PI, cell lab)

The basic assertion Sarafina makes is that the "new guard" of biomedical engineers begin with the biology and then introduce engineering concepts to address their research questions. These are cellular biomedical engineers who are engineers *of* biology because they work *within* biological systems to develop a particular outcome. She argues that the "old guard" begins with the engineering and then applies it to the biology. This approach to biomedical engineering uses the principles of mathematics and physics to design tools that can be used on biological processes. They are engineers *for* biology because their research results in the development of applications to be used *on* biological systems to elicit a specific outcome.

All of the junior biomedical device engineers interviewed in this study agreed with the statement that it is more difficult to teach or learn engineering than it is to teach or learn biology. The primary rationale given for this ultimately resides in the belief that engineering holds a higher epistemic value than biology. One Ph.D. student interview participant expressed strong support for the statement and identified the key pedagogical tension between the two disciplines.

> I 700% agree with that statement…I spent four years learning engineering, and right now I'm just refining my skills with science. I think it's easier to teach biology to an engineer…I think with biology you can just buy a book and read about it. And that's for the most part what I've been doing…it's just a lot of memorization. But with engineering there's almost no memorization. You can know the formulas, but unless you know how to apply the formulas, you won't know how to solve the problem on the spot.
>
> (Fahad, Ph.D. student, device lab)

The perceived difference between biology and engineering is that the former simply requires memorization whereas the latter is about a whole way of thinking. The engineering way of thinking is often associated with the use of mathematics.

The value that biomedical device engineers place on the use of mathematics in their laboratory activities is at the core of why they believe engineering is more difficult to teach or learn than biology. One biomedical device engineering postdoc argued, "The skill sets and abilities demanded from engineering courses and traditional science courses are different … It's just harder to gain one than the other." The emphasis that biomedical device engineers place on the importance of using math in the laboratory is an attempt to legitimize their credibility among others who value traditional engineering practices. Some researchers who work in biomedical device engineering laboratories, who are trained in classic engineering fields such as mechanical engineering or electrical engineering, are leery of the mathematical skills those trained in biomedical engineering bring to the lab. One postdoc scholar working in an ultrasound laboratory, with an undergraduate degree in physics and a Ph.D. is electrical engineering, commented on the perceived value of earning an undergraduate biomedical engineering degree.

> A lot of times with undergraduate biomedical engineers, there's just too much breadth in the program, and they never get the depth they need. In general, I would say all the Ph.D. students I've known in biomedical engineering it's more like, if you say your undergrad is in biomedical engineering, that's seen as a weakness. Or we look at (what) our students in biomedical engineering know, or what they don't know or what they can't do, and it's like, oh my God, these BME undergrads aren't getting the real math skills that they need.
>
> (Emily, postdoc, device lab)

The need for strong mathematical skills among biomedical device engineers is truly required if they are to build novel applications that are robust, efficient, and accurate. The challenge, however, is not to emphasize the value of mathematical knowledge over that of biological knowledge. There is a need to have proper knowledge of both areas represented in biomedical device laboratories to best safeguard human wellbeing.

6.3.2 The Modularization of Biology

The emphasis given to mathematical ability in biomedical engineering reflects the push some have made for expanding the use of quantitative biology methods. Such methods seek to

create predictive models based on fundamental principles that govern living systems through the use of mathematics, statistics, or computational techniques (Howard, 2014). These methods, however, risk transforming multidimensional physiological functions into discrete parts within an active system. The process of attempting to simplify biological operations further removes biomedical device engineers from the physical reality of patients by eliminating the holistic knowledge needed to safely navigate biological complexity when designing novel technologies. The quantification of biology removes the transparency that biomedical device engineers must maintain into the physiology of the human body.

There is an overall epistemic disposition in biomedical device engineering to approach the teaching of biology from within the context of modularity. This mentality is likely the result of traditional engineering values infiltrating biomedical engineering spaces. For example, in an interview with a biomedical device Ph.D. student, who has a background in electrical engineering, he expressed a desire to find a way to remove and replace individual biological elements as a part of his experimental designs.

> An analogy I give is if you're an electrical engineer, and you're given a radio that's broken, you have a circuit diagram where I have to text X, Y, and Z. I know I need to figure out a way to make this work, and I can isolate the problem fairly quickly to resistor X or whatever, and then you can swap it out and you're good to go. We don't really have that in biology.
>
> (Dhruv, Ph.D. student, device lab)

Since biology has yet to be fully quantified, and there is no equivalent circuit diagram available for use to manage biological (dys)function, many biomedical device engineers like Dhruv instead use a computer program called SimBiology[39] as a part of their design activities.

[39] SimBiology provides applications and programmatic tools which engineers can use to model, simulate, and analyze dynamic biological systems (MathWorks, 2020). This program is based on the MATLAB proprietary language developed by MathWorks which engineers use to plot functions and data, implement algorithms, create user interfaces, and interact with programs written in other languages.

The concern with using computer programs to represent biological functionality in experimental designs is that they serve as knowledge stand-ins for a body of knowledge we have yet to fully understand. However, for biomedical device engineers, they are seen as invaluable tools that help fill knowledge gaps in their attempts to develop novel applications. In an interview with Hisato, he expressed why he believes biomedical device engineers should increase their use of computational biology programs such as SimBiology.

> If you want to come up with an entirely new application, there's no real set computational pipeline to do so. It has to be done experimentally…but what I propose is a lot of it could be done through a computational approach. And because you can take out a lot of the experimental components, and you can turn them into computational components, that means the process of coming up with new applications is that much more streamlined because it requires less hands-on work. You can just let a computer do the work.
>
> (Hisato Ph.D. student, device lab)

The concern with using computational programs such as SimBiology is that it ultimately subjects biological complexity to a process of black-boxing, which removes transparency into its functionality. This process is happening without researchers reflecting on the potential values implications that such epistemological black-boxing suggests. However, interventions that encourage this type of reflection must be implemented at the laboratory level, and to ensure their effectiveness, they need reinforcement at the institutional level.

The laboratory R&D activities of biomedical device engineers present consequences for the values of responsibility and transparency. The privileging of engineering and mathematics knowledge over that of biological knowledge has critical implications for researchers who develop data models and software applications. Laboratory practices engaged in the abstraction of physiological processes risk the continued safety of patients receiving treatment using these devices. Biomedical device engineering laboratories must maintain transparency into biological complexity throughout the design process to protect the safety of patients.

CHAPTER 7: DISCUSSION

The results of this study demonstrate how the design of novel biomedical technologies by university-based biomedical engineering laboratories is a sociotechnical process imbued with values at every stage. These values manifest because of the broader institutional context, made up of the triple helix (Etzkowitz & Leydesdorff, 1995) set of actors from government, industry, and university, that laboratories are situated. This study also demonstrates how actors from the domain of healthcare influence, or do not influence enough, the design practices of biomedical engineering laboratories. Interactions among these actors have direct and indirect influences on how biomedical engineers enact values throughout the design process, and these values shape the perceptions and actions of biomedical engineers when prioritizing laboratory R&D activities.

This project finds that the way biomedical engineers engage in activities present implications for the values of responsibility and transparency. These values relate to their role as designers of biomedical technology; a role which impacts how technologies are designed (Winner, 1980; Nissenbaum, 2001; Knobel & Bowker, 2011, Shilton, 2011; 2018b; Friedman, Kahn & Borning, 2013). The values of responsibility and transparency have moral import (Manders-Huits, 2011) that suggest biomedical engineers, as designers of technology, have a moral duty to protect the wellbeing of patients who will eventually use novel biomedical technologies for treatment. This translates into needing to perform actions in the laboratory that adhere to these ethical duties.

This project also indicates the critical importance of considering values dimensions (i.e. sources, attributes) in laboratory design contexts (Shilton, Koepfler & Fleischan, 2013; 2014). For instance, the source of the value implications for biomedical engineering laboratories differ based on the type of technology (and therefore stage of development) a biomedical engineering laboratory develops. This speaks to how design interventions need to be implemented differently

for each type of laboratory group. Suggested interventions for cellular biomedical engineers must be ground in the fact they develop cell-based technologies for which many elements of the system are new and novel. Similarly, design interventions for biomedical device engineers need to be rooted in the fact they develop device-based technologies for which only some elements are new, but are also intended for integration with elements already used in clinical settings. What would make for the ethical design practices for one type of biomedical engineering laboratory would not necessarily make the same for another type of laboratory.

The next two sections of this chapter will conclude parts of this project by summarizing answers to the first two research questions presented in chapter one. The last section of this chapter suggests areas for future research. Findings which answer the third research question are presented in the final chapter of this dissertation.

7.1 How Values Impact the Design of Novel Biomedical Technologies

This research question is answered in two parts. The first requires consideration of the origins of the values found in biomedical engineering laboratories. The way that certain values have emerged in the discipline of biomedical engineering suggests different implications for the design practices of both cellular biomedical engineering laboratories and biomedical device engineering laboratories. The second is found by locating where along the translational roadmap each biomedical engineering laboratory is primarily situated. The act of explicitly locating biomedical engineering laboratories in this way has not been done before in the literature, but works to uncover critical values issues related to the design practices of each group of researchers. The location of a biomedical engineering laboratory is determined by the type of novel biomedical technology a group designs, and the practices used in their development, and ultimately provides insight into how values impact design practices. Both parts of the answer to the initial question are answered in conjunction, with cellular biomedical engineering

laboratories addressed first, and are then followed by those for biomedical device engineering laboratories.

One critical source of values is the disciplinary context in which laboratories are located. Biomedical engineering is an emerging (inter)discipline that brings together the disciplines of biology and engineering. Each discipline has its own culture, ways of knowing, and values (Baily, 1977; Traweek, 1988; Calvert & Fujimura, 2011). In biomedical engineering, the bringing together of biology and engineering produces values tensions based on differences in their epistemic cultures (Knorr-Cetina, 1999). Tensions are rooted in a history where scientific disciplines are thought of hierarchically, and where those at the top are thought to have more status and authority in making truth claims (Cole, 1983; Simonton, 2018). Contemporary depictions of this hierarchy place mathematics towards the top and biology towards the bottom. Since engineering-based knowledge claims are justified using mathematics, biomedical engineers likely value engineering research practices more than biological research practices.

The devaluing of biology-based practices is a trait shared by cellular biomedical engineering laboratories as well as biomedical device engineering laboratories. Although, the way in which this devaluing is expressed, and therefore impacts the design of their respective novel technologies, differs among groups. The laboratory R&D activities of cellular biomedical engineers are largely characteristic of what some scholars (Bush, 1945; Stokes, 1997) classify as pure/basic science. They often seek out answers to hypothesis-based questions and need to find answers about fundamental biological phenomena as they design novel cell-based technologies. The laboratory practices of cellular biomedical engineers are those associated with stage T0 along the translational roadmap. This is the basic research stage composed of preclinical studies and attempts to prove a valid proof of concept. This translational location, along with the emerging values of biomedical engineering, shapes how the values of cellular biomedical

engineering laboratories impact the design of novel cell-based technologies.

This study finds that the influence of market-based values impact research practices much further upstream than previously thought (Bush, 1945; Stokes, 1997). The laboratory practices of cellular biomedical engineering laboratories fall into what Stokes (1997) identifies as the "pure basic research" quadrant. Activities in this quadrant are thought of as generally immune to market forces due to their focus on knowledge exploration. The results of this project indicate that the effect of market logics is felt by cellular biomedical engineers at the earliest stages of the technological design process. These influences affect values in implicit ways, suggesting that group values are shaped by more than just what is typically associated with "pure" basic science.

Cellular biomedical engineering laboratories are located in departments of biomedical engineering and are housed in colleges of engineering. This study brings new understanding to how cellular biomedical engineering laboratories work in environments dominated by engineering norms and values, and because of this, cellular biomedical engineers express a desire to be more like engineers even though they self-identify as scientists. Cell-based laboratories attempt to position their technological design activities as working towards application, and utility, and solutions. The pressure to meet such objectives not only come from a disciplinary culture that values application, but also from institutional actors (e.g., NIH) who want to see translatable outcomes. However, an emphasis on application and translation, does not align with the type of actions and values regularly found in cellular biomedical engineering laboratories. Efforts to force an alignment of values between institutional actors and early-stage laboratory researchers result in the type of values implications addressed in Section 8.2.

New information about the values that different groups of biomedical engineers have for biology were also found in this project. For instance, biomedical device engineering laboratories express a devaluing of biology, and physiological complexity, that impacts their design of novel

device-based technologies. However, unlike cellular biomedical engineers, biomedical device engineers are more likely to self-identify as engineers instead of scientists. This reflects the type of laboratory R&D activities this group performs, and they characterize those most often associated with engineering practice. Biomedical device engineers want to solve for physiological problems by developing tools, that use data and mathematical equations to represent biology complexity, and that give them power and control over this functionality. The later stage translational location of these researchers, paired with the complimentary emerging values found in biomedical engineering, shapes how the values of biomedical device engineering laboratories impact the design of novel device-based technologies.

Biomedical device engineering laboratories are located in departments and colleges that align with the values associated with engineering practices. Biomedical device engineering laboratories know they work with technologies that have achieved translational success. They position their technological design activities as working towards the improvement or optimization of devices, and do so by developing novel applications intended for integration with clinical devices. However, having value alignment with broader institutional actors, does not necessarily result ethical design practices. Instead, it suggests these actors share the same problematic perceptions and attitudes. Biomedical device engineering laboratories design novel devices in an institutional context that implicitly supports ethically questionably design practices. The design practices of biomedical device engineering laboratories suggest certain values implications and are discussed in the next section.

7.2 Suggested Values Implications of Biomedical Engineering Laboratory Practices

Situating laboratory design practices along the translational roadmap provides critical insight into the institutional influences (i.e., core reactor groups) that shape the design process. This project presents the first efforts to model biomedical engineering laboratories as STINs.

This mapping process found that biomedical engineering laboratories share the same core reactor groups, but the influence of each core reactor group is experienced differently by the type of laboratory. Influences were found to inform how biomedical engineering laboratories work towards defined project priorities. The way that each group of biomedical engineers relates to the type of novel technology they develop, to how biological knowledge is treated in the laboratory, to the status of researchers in the discipline of biomedical engineering, all these factors impact their laboratory design practices. Both cellular biomedical engineering laboratories and biomedical device engineering laboratories conduct activities which suggest implications for the values of responsibility and transparency.

Cellular biomedical engineering laboratories resist labeling their laboratory developments as technological developments, and this is informed by their perception that novel technologies only exist once they transcend the boundary of the laboratory. Specifically, that a cell-based biomedical technology is not a technology until it is used in a clinical setting. This perception is shaped in part by the value for application that is expressed in the discipline of biomedical engineering. This emerging discipline is rooted in colleges of engineering where standard engineering practices, based on the "need-know-how-solve" method, is highly valued (Kosky, et al., 2013). Since cellular biomedical engineering laboratories do not adopt this problem-solving approach, and cannot guarantee the immediate applicability of their innovations, perceiving themselves as designers of technology is hindered. This also adversely affects their acceptance as responsible actors in the design of safe and secure novel biomedical technologies.

The desire to produce a tangible product, and to recruit industry partners, also directly impacts how cellular biomedical engineering laboratories think about the end-results of their laboratory activities. They think about getting patents, and establishing start-ups, because that is what industry stakeholders find attractive. Commercial entities want a novel cellular technology

that is potentially marketable, and for which the production can be upscaled. However, in the rush to get patent, cellular biomedical engineering laboratories likely end up black-boxing certain biological knowledge, like that of the CRISPR-Cas9 System, into something that is patentable. This results in a loss of transparency into the complexity of biological functionality, not only for future researchers, who will no longer need to learn how certain cell-based technical elements work, but also for other researchers in the field. Proprietary knowledge is not easily accessible by others who research similar phenomena. Cellular biomedical engineers being to position translational intermediaries (e.g., industry partners) as the perceived end users of the novel cell-based technologies they develop, when truly, patients are the end users. This implicit misidentification of the end user decreases transparency into considering patient healthcare needs throughout the novel cellular technology design process.

Cellular biomedical engineering laboratories are also removed from the realities of clinical healthcare settings, both in terms of their upstream location along the translational roadmap, and the difficult experience of trying to recruit clinical research partners. This difficulty increases when a university, with a biomedical engineering department, also does not have an affiliated medical campus. Little opportunity exists for cellular biomedical engineers to gain appreciation for what clinicians want to see, and most importantly, what patients need to have included in emerging cell-based technologies. This distance from the healthcare context, both physically and epistemologically, contributes to a decreased sense of responsibility among cellular biomedical engineers to design novel cell-based technologies while considering potential negative impacts.

Biomedical device engineering laboratories think of their R&D activities as optimizing or improving already clinically translated technologies. Such laboratories develop new data models, and software applications, that are intended for integration with clinically used devices. The

perception of biomedical device engineers is that the integration of these new elements with clinical devices will not adversely impact how they are used in healthcare settings. Since the core elements of the device were previously declared safe by the FDA, such "advancing" of the technology is not seen as problematic. This viewpoint, however, minimizes consideration of potential adverse reactions when novel, and not-so-novel technological elements, combine into a single device. Biomedical device engineering laboratories have a responsibility to reflect on the possibility of novel applications resulting in harmful impacts once they are used by patients.

The relationship biomedical device engineering laboratories have to biology is complicated, and it suggests critical implications for how novel biomedical devices are designed. This relationship is informed by the values of the surrounding disciplinary culture (Traweek, 1988; Knorr-Cetina, 1999; Ma, et al., 2017), and is reinforced when using standard engineering practices in the laboratory. The broader cultural context of biomedical engineering is one that values engineering knowledge more than biological knowledge. The culture reflects a hierarchal disposition to regard scientific practice by placing biology towards the bottom, and where mathematics, emblematic of engineering practice, is placed at the top. The epistemological devaluing of biology is reinforced by attitudes and opinions, such as learning biology is a simple act of memorization, and that learning engineering required a "whole way of thinking." These values are reified in biomedical device engineering laboratory practices that rely on the abstraction of biological processes into data points and mathematical equations. These activities make the unknowns of biological action containable and controllable, which in turn, makes them definable and solvable. The trade-off, however, is a loss of transparency into dynamic and complex physiological processes, and decreased insight into physiological functions. This exchange in priorities may result designing biomedical devices that are less safe for future patient use.

7.3 Future Research

Future studies that examine the technological design practices of biomedical engineering laboratories should continue with modeling this system as a STIN. This project focused primarily on step one, identifying a relevant population on system interactors, and step two, identifying core reactor groups, but steps three through eight would provide invaluable insights into the values and ethics of biomedical engineering laboratories. Although this project hints at elements included in steps three through six of the modeling activity, a thorough investigation of each step would prove beneficial. Specifically, step four calls for identifying excluded actors and undesired interactions, and this study found healthcare actors are largely absent from the design process of novel biomedical technologies. They act almost like indirect stakeholders, but their healthcare needs should serve as a top, if not *the*, priority as novel biomedical technologies are designed. Patients are a vulnerable group of technological users. They are at the mercy of the people, groups, and institutions responsible for their healthcare, and they must be able to trust the technologies used in their treatment to protect their wellbeing.

The STIN modeling activity also includes step seven, which is identifying system architectural points, and step eight, about mapping architectural choice points to sociotechnical characteristics. In this project, steps one and two were used to map biomedical engineering laboratories as STINs, and this compliments the conceptual approach of VSD that is part one of its three-prong iterative analysis. The other two prongs, empirical and technical, are best answered by mapping additional STIN steps. Specifically, steps seven and eight speak to the technical framework of VSD, and focuses on existing technical properties and mechanisms of a system, and how it can be used or altered to support social values. The identification of the architectural points, and the related choices points, was not possible in this project due to the novelty of the discussed biomedical technologies. Finding these points would require additional

examination of the laboratory R&D activities of biomedical engineering laboratories. More field-site observation hours would help in determining which technical properties and mechanisms of novel biomedical technologies already exist, and which are in the process of development. This would be easier to perform in device-based laboratories, however, since researchers work with post-translational technologies composed of already existing technical system elements. This should not suggest modeling steps seven and eight of a cellular biomedical engineering laboratory is impossible, but it would require a significant time investment to identify where choice points exist, and emerge, as these novel systems evolve.

Additional values and design studies of biomedical engineering laboratories, or of scientific laboratories engaged in similar practices, should explicitly insert ethical justifications to support moral claims. The ethical context must be made clear when the laboratory activities of researchers suggest specific values implications. Values of moral import are key to VSD approaches because these approaches often suggest interventions for laboratory practices. Interventions based on ethical foundations provide more holistic ways to address ethical aspects of a group's design process. For example, values and design studies often focus on the potential negative consequences when using a technology in society. This results in designers of technologies becoming the focus of interventionist studies so they are able to avoid developing technologies embodied with harmful properties. This approach should continue, and be complemented with interventionist studies focused on the duties and values of designers, who, while serving in these roles, enact certain values.

The suggestions that values and design scholars from any tradition, not just VSD, engage in ethical analysis, is easier said than done. Scholars often come from the intellectual traditions of HCI, CSCW, LIS, among others, where ethical training is not a part of the standard discourse. One side may support more use of ethical theory within VSD analysis, but others may think this

knowledge base is best left to the philosophical experts. Perhaps the answer is for more collaboration between values and design researchers and philosophical experts, where neither needs to be the expert of the others domain, but where shared knowledge is leveraged for better ethical results.

CHAPTER 8: VALUE IMPLICATIONS AND DESIGN INTERVENTIONS

The purpose of this chapter is to reflect on the values of two groups of university-based biomedical engineering laboratories as they design novel biomedical technologies. This reflective activity serves two primary goals: to identify the values implications of these design practices and to suggest interventions to mitigate these implications. The findings of this project suggest that both cellular biomedical engineers and biomedical device engineers engage in a complex network of scientific activity (Callon, 1984; Latour, 1987; Law 1992). Their laboratory practices present values implications unique to their starting location on the NIH's translational roadmap. These locations represent how far along each type of technology, either cell-based or device-based, is in the development process. They also work to situate each type of laboratory group within the broader institutional context in which they design novel biomedical technologies.

The values in the R&D activities of both groups are shaped by multiple contextual factors, all of which are greater and more powerful than any single researcher or laboratory. This limits the ability of any individual or laboratory to address values implications themselves. Many of the following recommended design interventions for laboratories will likely be hindered or limited without also intervening on a broader scale; therefore, interventions on the institutional level are also presented. The interventions presented here are akin to the type of values interventions that values and design scholars such as Shilton (2011; 2013; 2018b) and others (Manders-Huits & Zimmer, 2012; van Wynsberghe & Robbins, 2014; Shilton & Anderson, 2017) advocate for in their research. Design interventions need to make explicit those values that are otherwise implicit throughout the design process.

The translational stage of novel biomedical technology development speaks to Collingridge's double-bind problem and the difficulty of implementing design interventions that

take social impacts into account (Figure 20). Cellular biomedical engineers are in the earliest design stages of novel cellular technologies, which suggests they have the most power to make changes. However, as this dissertation reveals, their laboratories are embedded in a context where very powerful actors shape the researchers' power to act. Their ability to act may be considerably restricted because of these strong influences. Researchers may still be able to exercise power at this stage, but they are likely to face trade-offs that compromise their careers or other goals they value.

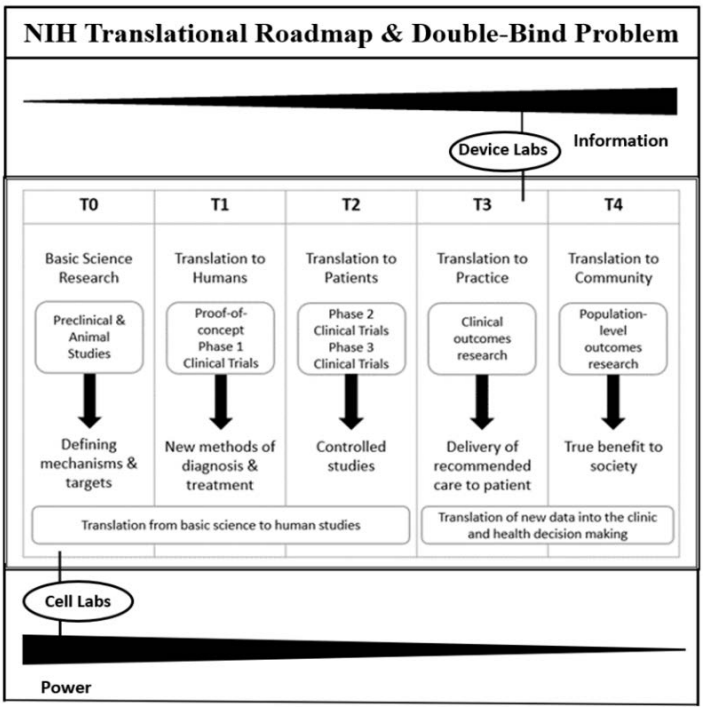


Figure 20

(NIH Translational Roadmap: Adapted from Liverman, et al., (2013)

The upstream location of cellular biomedical engineering laboratories also indicate they do not have all the information necessary to know how a particular technology will impact society. In contrast, biomedical device engineers do have more information about the impacts caused by the type of technologies they design. However, they may not have all the information necessary to make changes, or they may not consider what is already known. Reflection will also be less likely to happen without support from institutional actors and the resources they provide.

The double-bind problem of information and power reaches to the heart of how technological interventions that address the ethics of technology always seem "too early" or "too late" in the design process (Kudina & Verbeek, 2019). Such interventions focus only on changing design practices insofar as they will produce less harmful technologies once they are deployed. Concerns about the potentially negative impacts of a technology are, of course, important, but ethics-based design interventions should also consider the actions of designers themselves from an ethical perspective. The morality of a technology resides not only in its use but also in the way it is created. From this perspective, the focus is more on the ethics of the design context itself, and who does and does not have power, which extends far beyond individuals or even laboratories. Having enough information about potential negative impacts, which are impossible to predict, matters less during the design process, especially the early-stages, than the morality of influential institutional actors.

Ethics-based design interventions should consider the morality of design actions themselves within their particular contexts. The actions of designers during the process of technological development should be considered right or wrong under a series of rules and duty-based expectations. For example, each actor in a biomedical engineering sociotechnical system fulfills a particular role and performs certain duties. However, these roles and duties are also shaped by surrounding institutional influences. Responsibility as a duty, for instance, should be about designers and stakeholders behaving as responsible actors engaged in responsible actions. Nevertheless, within a sociotechnical system, multiple stakeholders are involved in the design process and each one has their own, albeit interconnected, goals and aims. All actors in this system, however, share in their collective responsibility (Miller, 2018) or distributed moral responsibility (Floridi, 2016; Chandler, 2017) to act in ethical ways throughout the design process. Therefore, ethical interventions must question which values and virtues the actors

serving in these roles and performing these duties must enact within the design process. Such interventions should happen alongside interventions that focus primarily on the consequences of using a deployed technology.

The specific values interventions proposed in this chapter consider the values of responsibility and transparency as they are grounded in a deontologist ethical perspective. The emphasis here is on the actions of designers in their laboratories as they function within a sociotechnical biomedical engineering context. Although it is important to consider the potential future consequences of using a biomedical technology, doing so may prove fruitless the more upstream a particular technology is in the design process. The ethical interventions proposed in this chapter take issue with the roles of biomedical engineers as designers of technology and their duty to act ethically while designing novel technologies. The focus here is more on sociotechnical actors engaged in the design process than on the potential consequences that may result from using novel biomedical technologies once they are deployed. Interventions are also proposed at both the laboratory level and the institutional level in recognition of the sociotechnical context and the shared distributed moral responsibility of all involved actors.

This chapter is presented in four primary sections. The first section summarizes and discusses the values implications found in Chapter 5, based on the laboratory R&D activities of cellular biomedical engineers. The second section presents three proposed ethics-based interventions for the design practices of cellular biomedical engineers. These interventions address the values of responsibility and transparency and consider interventions at both the laboratory and institutional levels. The third section summarizes and discusses the values implications found in Chapter 6, based on the laboratory R&D activities of biomedical device engineers. The final section suggests two potential ethical interventions for the design practices of biomedical device engineers. Additionally, these interventions address the values of

responsibility and transparency and propose interventions at both laboratory and institutional levels.

8.1 Values Implications: Cellular Biomedical Engineers

The results of this study reveal that cellular biomedical engineers resist the label of "technology" to describe their novel technological developments. Although they recognize, to some extent, that their laboratory design activities contribute to the making of new biomedical technologies, the boundary for when something becomes a technology is often drawn around the laboratory walls. Specifically, laboratory developments become technologies once they are used to achieve clinical objectives (i.e., once they are used outside of the laboratory). Although clinical utility is positive, as it implies improvement of patient wellbeing, waiting for the utilization of a technology minimizes the role that cellular biomedical engineers play as designers of technology. This role minimization decreases the amount of responsibility that cellular biomedical engineers perceive to have in the design of ethical biomedical technologies. It also suggests that the posing of ethical questions does not need to happen until a technology is used outside the laboratory.

The distancing that cellular biomedical engineers invoke between themselves as designers of technology and the technologies they develop also reflects an internalized devaluing of early-stage or exploratory laboratory practices. Cellular biomedical engineers are stage T0 researchers engaged in what stakeholders understand as basic scientific laboratory activities. However, cellular biomedical engineers are also members of academic departments located within colleges of engineering. This situation results in value clashes between basic versus applied research activities. The values associated with applied research better align with engineering practices, and because of the location of cellular biomedical engineering laboratories within engineering, they function in a disciplinary culture that values applied research more than

basic research. Cellular biomedical engineers must accept that, as stage T0 researchers, they also play a critical role in the design of novel biomedical technologies.

Furthermore, the concept of translational medicine is used within biomedical engineering communities in a way that reinforces the basic versus applied hierarchical values system. The term “translation” is used as a stand-in for “applied” and suggests that valuable novel biomedical technologies are those that are translated from bench to bedside and are used in clinical settings. University-based biomedical researchers are trained to view their work activities within this framework, and doing so implicitly encourages laboratories engaged in basic scientific practices to consider producing a tangible product. The goal of translation for basic biomedical research is to result in positive patient health impacts at the end of the development process. Implicit in this framework, however, is that biomedical innovations should be developed and marketed as quickly as possible. This expectation motivates some cellular biomedical engineering laboratories to describe their research as translational. The purpose of this is to send a message that cell-based laboratories are committed to the production of a tangible outcome because of their research projects.

However, as stage T0 researchers, cellular biomedical engineers have yet to engage with the necessary stakeholders that can usher biomedical laboratory developments into the clinic. Describing a cellular biomedical engineering laboratory as a translational laboratory misidentifies the actual stage of technological development where the group is located. Cellular biomedical engineers do not consider patient impacts in the way that using the term “translation” suggests. These laboratories prioritize the wants and needs of translational intermediaries—the actors that become involved in the development process well before a technology is ready for clinical use. The translational goals of cellular biomedical engineers then become what intermediaries, such as commercial entities or the FDA, want to see in potentially translatable

technologies.

The meaning of the term translation often becomes conflated by cellular biomedical engineers who use it more to mean the design of a “product” than the provision of “healthcare.” The trade-off that cellular biomedical engineers make in their quest to prove the value of a technology’s potential applicability is using translation to mean *faster to market* rather than *faster to care.* The pressure that cellular biomedical engineering laboratories experience to ensure that their novel technologies are upscaled and marketed adversely impacts their relationship with translation. Cellular biomedical engineers use the term translation in a way that hinders the *transparency* of its intended meaning.

Often, the clinical application of a novel cell-based biomedical technology is not what serves as a primary driver of a particular development project. The specifics of how a novel technology will be used by physicians to treat patients in clinical settings is largely unknown. Cellular biomedical engineering laboratories are removed from the clinical context both physically and epistemologically. Cellular biomedical engineers do not work with patients given their stage T0 locations along the translational roadmap, and research partnerships with clinicians seem rare and more symbolic than collaborative when they do exist. The perception that cellular biomedical engineers have of who serves as the imagined end user of their novel technologies is adversely impacted by their distance from clinical realities.

Since novel cellular biomedical technologies are 10–20 years away from clinical use, translational intermediaries, such as commercial entities and the FDA, become the de facto (albeit implicit) imagined end users of these products. Cellular biomedical engineers seek to attract industry partners that will take over the production and marketing of their novel developments. These partners assume responsibility for the costs associated with production as well as with gaining FDA approval to market the product to customers in the healthcare industry.

Therefore, what industry partners want to see in a developing cell-based technology becomes the design focus of the laboratory.

Cellular biomedical engineers also see industry partners as the actors responsible for considering how a novel cell-based technology might be used. This perception defaults to an implicit assumption among cellular biomedical engineers that intermediaries are responsible for any potential negative impacts from the use of novel cell-based technologies. More importantly, however, this assumption serves to lessen (or remove completely?) the feeling of responsibility that cellular biomedical engineers believe they have to worry about potential social impacts. One important way to bridge this responsibility gap would be the increase of connections that cellular biomedical engineering laboratories have with actors in healthcare (i.e., patients, physicians). Cellular biomedical engineers have a *responsibility* to design novel cell-based technologies where patients are the intended primary end user. Designing novel biomedical technologies for the needs of patients will help avoid potentially negative social impacts from their use.

8.2 Values Interventions: Cellular Biomedical Engineers

The values of responsibility and transparency are adversely implicated by the laboratory R&D activities of cellular biomedical engineers. Their physical and epistemological distance from clinical healthcare environments decreases their awareness that, as designers of technology, they are ethically accountable for their actions in the laboratory. This distance also negatively impacts their perception of patients as the end users of the novel cell-based technologies they design. The following proposes three interventions that address these values implications at both the laboratory and institutional levels. The ethical position that justifies each intervention is also discussed.

Intervention No. 1: Explicitly refer to laboratory research developments as technological developments.

The perception of what a technology is differs greatly among individual cellular biomedical engineers. Even members of the same laboratory group might disagree if they are or are not in the process of designing something that could be classified as a biomedical technology. Part of the resistance that individuals have toward using the word “technology” to describe their research is that what they are developing is not yet regularly used in healthcare settings. The lack of application of a novel development suggests to cellular biomedical engineers that they have yet to successfully translate their research into the clinic. This linguistical distancing also allows for ethical distancing between cellular biomedical engineers and the sense of responsibility they feel to design ethical technologies. Cellular biomedical engineers must regard their laboratory practices as a critical part of the technology making process.

Cellular biomedical engineers have a role-based duty to act responsibly while designing novel biomedical technologies. Serving in this role means having a moral obligation to perform actions that adhere to a particular set of rules. The values of biomedical engineering as a discipline (and as a sociotechnical system) should reinforce these ethical actions through rules explicitly recognizing the value of responsibility for those who design biomedical technologies. Explicit reference to laboratory developments as technological developments would strengthen this value within biomedical engineering culture.

Laboratories could strengthen this value by adjusting the way they communicate about their research developments with other lab members. For example, individual members regularly present the findings of their research projects to other members during regularly scheduled group meetings. Presenters should be encouraged to discuss their work in the context of technology. Additionally, as laboratory group members engage in more informal discussions with their colleagues throughout the day, they should include technology-based terminologies when applicable. Cellular biomedical engineers who learn how to speak about laboratory developments

as technological developments will increase the visibility of stage T0 biomedical engineers as designers of technology. Doing so will foster a stronger sense of responsibility among cellular biomedical engineering laboratories to engage ethical design practices.

The expectation that cell-based projects be presented as technologies should also be reinforced in two environments beyond the laboratory. First, the language used to refer to cellular biomedical engineering projects is inconsistent between professional biomedical engineering associations. For example, genetic engineering may be referred to as a biotechnology by one association but as a gene-editing process by another. This inconsistent language sends the wrong message about responsibility to cellular biomedical engineers. Professional associations should work toward a standardized language to refer to cellular biomedical technologies. Second, academic biomedical engineering departments should either lead or complement this process by formalizing a technological taxonomy within the discipline. The results of this study suggest that departments use a variety of different terms to describe the same type of cell-based technologies. Greater institutionalization of the language used to categorize novel biomedical technologies promotes greater recognition of cellular biomedical engineers as designers of technology. Additionally, this validates that laboratory developments are technological developments regardless of their stage of translation.

Intervention No. 2: Use the term "translation" to emphasize the clinical provision of care instead of the manufacture of a product.

There are serious values implications when cellular biomedical engineering laboratories lack regular interactions with actors of the healthcare community. The distance experienced between these stakeholders adversely affects the design process of novel cell-based systems. This is reflected in the way the term translation is used by cellular biomedical engineers to discuss the end goal of turning research outputs into products to be sold. Additionally, this is

demonstrated by cellular biomedical engineers who express greater awareness of what is needed for successful technology transfer than an understanding of how novel cell-based systems could eventually be used in clinical settings. The reality is that achieving successful technology transfer of a novel cell-based system is easier to envision than it is to imagine how a yet-to-be-actualized technology would be used by a physician. However, the marketability of the final cellular biomedical technology should not serve as the primary driver of its development.

The conflated use of the term translation presents an ethical risk to the wellbeing of patients. The concept of translation at its best speaks to the health benefits patients receive when laboratory innovations are fully actualized within the clinic. However, the conflated use of the term translation ultimately positions patients to serve as mere means to an end among cellular biomedical engineers. In moral law, Kant argues that humans are required to never treat others as merely a means to an end. Human action is only good if it is done from a sense of duty, where a duty is not based on self-interest or with concern for the results that follow. When translation is used to refer to a product instead of the provision of care, the needs of patients are used to make a cellular biomedical technology seem more appealing to industry partners. Patients serve as a means to an end in which cellular biomedical engineers make the case as to why commercial entities should stake a claim in the production of their novel cellular technologies.

One of the best ways that cellular biomedical engineering laboratories could combat this ethical issue is by establishing regular connections with healthcare stakeholders. Ideally, cell-based labs would have a physician collaborator associated with each research project. These collaborations would need to extend beyond the symbolic addition of names on funding applications, but instead be about the true exchange of knowledge during the design process. Unfortunately, for universities lacking a college of medicine, these relationships are difficult to establish. Should a cell-based laboratory foster a relationship with a non-university-affiliated

physician or clinical group, regular meetings may be limited or inconsistent. Additional messaging is also needed in laboratory environments to keep clinical impacts at the forefront of consideration. Sharing more healthcare-focused communications in laboratories would work to recenter clinical translation rather than product translation as the ultimate end goal.

The initial use of the term translational medicine indicated the development of pharmaceutical treatments. The term is now evolving to reference all types of health-focused applications. In other words, how translation refers to emerging biomedical technologies is itself still emerging, but now is the time to clarify what it means from a values and ethics perspective. The field of biomedical engineering can play an important role in the shaping of which values are suggested when cellular biomedical engineers describe their novel technology projects as translatable. Greater awareness about clinical practices should be communicated within biomedical engineering departments. Departments should foster deep connections and partnerships with clinical partners, and healthcare systems should engage in outreach activities on par with technology transfer offices. Clinical realities need to have a presence in biomedical engineering departments and laboratories. Working closely with healthcare systems and clinicians plays a critical role in bridging knowledge gaps between cellular biomedical engineers as designers of technology and patients in need of safe and ethical care.

Intervention No. 3: Contextualize patients as the end users of novel biomedical technologies throughout the entire development process.

Laboratory group meetings again serve as an important environment where cellular biomedical engineers can express to others their value commitments. These meetings are where the results of experiments and tests are presented and discussed among all team members. The results are even likely heard for the first time by the laboratory PI These meetings provide a space for researchers to discuss their design process as it was performed individually or in

conjunction with other laboratory members. Presentations are somewhat formal in tone and the question-and-answer periods can be grueling for the speaker. All aspects of the experiments and design process can be challenged, clarified, and supported by other laboratory members. Many epistemic functions act out in these environments, but often, little attention is devoted to the broader context in which the novel cell-based system is developed. However, this is likely one of the best environments where bringing attention back to the clinical context would be beneficial. The risk for cellular biomedical engineers in these meetings is that it is quite easy to become lost in the details of the data and to neglect regularly zooming out to reflect on results within the broader picture.

Little reflection on the potential real-world context in which novel cell-based technologies may one day be implemented results in little to no focus on patients in laboratory discussions. Similar to how the use of the term translation presents an ethical risk to individual welfare, the lack of referencing patients, or not reflecting on potential patient impacts, presents ethical design risks. This suggests another way in which the Kantian view of moral law may be violated in laboratory activities. Patients are an end themselves and should be explicitly understood as a means in which cellular biomedical engineers perform their laboratory activities. However, making the presence of patients explicit in the laboratory environment suggests that they are not just a means but are also ends in themselves. The healthcare needs of patients should be reflected upon regularly throughout the entire design process.

During laboratory group meetings, cellular biomedical engineers must implement practices that maintain focus on patients as the end users of the novel biomedical technologies they develop. This not only prevents patients from serving as mere means to achieve other ends, but it also works to explicitly recognize the ethical design activities that cellular biomedical engineering already provides in protection of patient wellbeing. For example, when the Tango

Lab designs a quantum dot with a polymer coating, it does so because it wants to prevent harm to the person who will be treated with it one day in the future. However, this context becomes lost to some extent without explicit connections made to physiological processes and consideration of patient impacts outside the laboratory. Cellular biomedical engineers should make explicit connections between their research results and patient impacts during laboratory group meetings. These connections should emphasize a continued evaluation of the physiological compatibility expected of novel cell-based systems when used with patients.

Increased connections with healthcare providers will also help cellular biomedical engineers ensure that patients remain in the foreground of intended technological end users. As mentioned previously, recruitment of clinical collaborators can be difficult when development of novel cell-based technologies risk the perception of being more esoteric in design than practical in application. However, without regular input from healthcare stakeholders who either provide healthcare (i.e., clinicians) or receive healthcare (i.e., patients), cellular biomedical engineers risk losing sight of the intended application of their novel systems. More interaction is needed between cellular biomedical engineering laboratories and healthcare stakeholders so the former gains greater insight into how a novel system would be potentially administered to patients. Maintaining this awareness of patient reality would support ethical design practice where patients remain the intended end user of novel cellular biomedical technologies.

8.3 Values Implications: Biomedical Device Engineers

Biomedical device engineering laboratories are located at stage T3 along the translational roadmap. They work with post-translational biomedical devices to develop novel applications intended for integration with devices already used in clinical settings. Working to improve or optimize post-translational technologies instills in biomedical device engineers a false sense of security of their continued safe use. Biomedical devices such as MRI, ultrasound, and prosthetics

are already approved by the FDA for human use and for sale on the market. Therefore, biomedical device engineers who consider laboratory activities as simply improving or optimizing a device regard the core elements of the device as safe for continued human use. Additionally, the FDA may not require additional testing to demonstrate that biomedical devices remain just as safe and effective as they were before novel applications were introduced. Even in cases where the FDA may require additional clinical trials, such as those associated with the design of software as a medical device, biomedical device engineers are inclined to regard the core device as safe for patient use.

This assumption by biomedical device engineers that altered biomedical devices will remain safe and effective poses a risk to the wellbeing of patients. This assumption also minimalizes the biomedical device engineers' perception of themselves as key actors with a *responsibility* to protect patient safety and health. These researchers are a part a larger body of actors who share a collective responsibility to protect the wellbeing of patients. Since they have important information about how post-translation biomedical devices impact users, they should be encouraged to call on this information as part of their design practices. Biomedical device engineers have a *responsibility* to use this information to reassess core device safety and standards when developing novel applications.

The results of this study demonstrate how both cellular biomedical engineers and biomedical device engineers draw boundaries around what it means to be a scientist and what it means to be an engineer. Associated with these identities are values that suggest what it means to work with biology and what it means to work with engineering. Because engineering is closely associated with the use of mathematics, and since mathematics is ranked above biology on the hierarchy of scientific disciplines, engineering laboratory practices are held in higher regard than biological laboratory practices are. Biomedical device engineers self-identify as engineers, and

this perception shapes their approach when working with biological processes. For example, biomedical device engineers develop data models and software programs that turn complex biological processes into simplified abstractions. Such design practices are based on the engineering principle of problem-solving and where only so much biological knowledge is needed to produce a perceived solution to a given physiological problem.

Biomedical technological design activities that are based on a problem-solving design principle support laboratory developments that act upon biological processes (engineering *for* biology) rather than work within the complexity of biological phenomena (engineering *of* biology). There also appears to be little institutional incentive for biomedical engineers to learn more biology than is immediately necessary when designing novel applications. If biomedical engineering associations and departments continue to assert that learning biology is a simple practice in memorization, then technological design practices that reinforce this impression will limit biomedical device engineers from gaining a deeper understanding of and appreciation for complex biological processes. The result may be the design of novel biomedical devices that hinder the safety and wellbeing of patients. The concern for patients is that they will be treated with technologies without full *transparency* of the risks involved.

The value of having transparency into biological complexity is also implicated when biomedical device engineers apply a systems perspective to solve for biological problems (i.e., to fix a particular disease). For example, an electrical engineer, when faced with a broken appliance, will refer to a circuit diagram to isolate the broken component. Once the broken part is identified, the electrical engineer can simply replace it with a new part. This type of binary way of thinking reflects a systems perspective that uses a black-and-white method of solving an immediate problem. When a biomedical device engineer is faced with a malfunctioning biological system, there is a desire to transfer this way of thinking to solve for the physiological

problem. This approach is supported by calls within the biomedical engineering community to increase the quantification of biological processes.

Quantified biology uses equations to represent biological phenomena that can then be used to determine where in the body a particular physiological breakdown (i.e., health problem) is occurring. If the biomedical engineering community continues to further develop and implement this design approach, it will decrease the level of transparency it has into biological complexity. This decrease in transparency presents increased risks for patient wellbeing if the patients were to be treated with novel biomedical devices designed using a quantified biology approach. Biomedical device engineers must maintain *transparency* into complex biological processes in their design practices to best protect the health and safety of patients.

8.4 Values Interventions: Biomedical Device Engineers

The values of responsibility and transparency are negatively implicated by the laboratory R&D activities of biomedical device engineers. Working with post-translational technologies gives biomedical device engineers a false sense of security that these core devices remain safe for patient use once they are integrated with novel applications. However, biomedical device engineers have a responsibility to reflect on the potential negative impacts these altered devices present. These engineers also present a strong alignment with standard engineering practices and values, which results in the ethically problematic design of novel applications based on the oversimplification of complex biological processes via abstract representations. The following proposes two interventions that address these values implications, each suggesting actions to take at both the laboratory and the institutional levels. The ethical position used to justify each intervention is also discussed.

Intervention No. 1: Reflect on the continued safety of core biomedical devices when developing novel applications.

The importance of this proposed ethical intervention should not be minimized, but it should also be recognized how difficult such a proposition would be to truly implement. Reflective practices are not standard in most scientific disciplines. The reality is that there is little incentive among biomedical device engineers to engage in reflective design activities as they work on novel applications. Funding agencies want to provide financial support to projects that push the boundaries of technological innovation within healthcare, and a continued focus on the future rarely allows time for consideration of the past. The quest for novelty is what fuels all aspects of biomedical engineering R&D activities, and until the ethics of this value is questioned within a technological design context, contemplative laboratory practices will not be overtly encouraged.

The proposed use of reflective practices within biomedical device engineering laboratories speaks to the ethical duty that designers of such technology have when attempting to develop trustworthy devices. Their design actions in the laboratory are held to certain moral obligations based on their role as technological designers. The result of reflective laboratory practices in the context of novel biomedical device development is that any proposed changes to core device elements, such as increasing the size opening of an MRI machine (without impacting or improving diagnostic capability) will be resisted by manufacturers that do not wish to spend the time and money to make changes. However, what is ethically best for the mental wellbeing of patients would be making such a change to the device. Until contemplative activities are supported by biomedical engineering culture, the laboratory design practices of biomedical device engineers will be in moral violation. Their role as designers of technology gives them a duty to reflect on the continued safety of altered biomedical devices.

If the culture of biomedical engineering were to ever embrace the notion of implementing reflective practices, a proper incentive structure would need to be built to encourage such

actions. Laboratory PIs would need to determine that such activities were valued in individual laboratories, and funding agencies would need to support this via financial incentives. For example, one factor that biomedical device engineering laboratories consider as they determine their research project priorities is what type of projects funding agencies want to support. Since the desire for NIH funding is strongly sought among biomedical engineers, the NIH should consider offering funding opportunities in support of ethically reflective projects. Such funding could encourage comprehensive safety assessments of core devices that have been augmented with novel applications.

Intervention No. 2: Address the implicit devaluation of biology within biomedical engineering laboratories and discipline.

Biomedical device engineering laboratories would benefit from having more knowledge about biological processes as they design novel applications. Contemplating the best way to instill this knowledge among laboratory researchers proves to be an important challenge. Part of the solution would be achieved by addressing curricular deficits related to how biology and physiology are taught in biomedical engineering classrooms (see below). However, given the complexity of biological processes—and the fact that there are stand-alone programs in biology that provide this education—university-based biomedical device engineering laboratories should leverage this knowledge. Biomedical device engineering laboratory groups should consider the addition of a biologist to their teams. Similar to the type of values intervention proposed by Shilton (2010; 2011) for the inclusion of ethics advocates on technological design teams, the addition of a biologist to a biomedical device engineering laboratory would serve an important ethical role.

The primary purpose of an expert biologist joining a biomedical device engineering laboratory would be to ensure that biological considerations are a more routine part of the design

process. Shilton (2010) found in her work with a ubiquitous computing laboratory that ethics advocates could facilitate conversations among laboratory groups that serve to reveal ethical concerns. These concerns could then translate into prioritized design goals and lead to the construction of more ethical technologies. Rather than expect biomedical device engineers to know when and how complex biological processes might be implicated within a particular novel application design, the inclusion of a biology advocate would enable conversations that bring ethical implication to the forefront of the design process. The addition of a biologist to a biomedical device engineering laboratory would play an important ethical role whereby a values-oriented (pro-biology) approach would shape the development of ethical novel biomedical device applications.

There are two curricular areas in the discipline of biomedical engineering that need improvement from a values and ethics perspective. The first area relates to training biomedical engineers to contemplate physiological processes in the context of technological compatibility. In this project, I argue that biomedical device engineers should place more value on biology to better protect the wellbeing of patients. However, within this argument is an awareness that asking biomedical engineers to gain comprehensive biological knowledge themselves is unnecessary. Biomedical engineers are not biologists and should not be expected to become so; yet, where is the pedagogical line between teaching biology for biologists and teaching biology for biomedical engineers? How can biomedical engineers be taught biology in a way that does not reinforce the *biology as memorization* epistemological presumption? Although specifics about how to achieve this educational goal beyond the scope of this immediate project, it is essential from a values perspective that such a bias against biology be considered in future studies about biomedical engineering ethics.

The second curricular area within the discipline of biomedical engineering that requires

attention is the inclusion of some version of medical ethics training. The epistemological emphasis in biomedical engineering is on the engineering, but more emphasis is needed on the role that biomedical engineers play in healthcare. Whereas professional physicians are expected to adhere to the American Medical Association's Code of Medical Ethics,[40] professional biomedical engineers do not share many of these values in their own professional codes. Additionally, university-based biomedical engineers often receive inconsistent forms of ethics training. They are most likely to receive research ethics training, either sponsored by the university or in response to NIH mandates, but such training primarily addresses issues related to ethical data use and the publication of reproducible research. Of course, this type of ethics training is important and should be standardized in the curriculum, but biomedical engineers also need to receive some form of social ethics training focused on patients and healthcare impacts.

This chapter presents the values implications found in this project when studying the laboratory R&D activities of cellular biomedical engineers and biomedical device engineers. The values of responsibility and transparency were found to be adversely impacted by the design practices of both groups of biomedical engineers. Three ethical interventions were proposed for cellular biomedical engineering, and two ethical interventions were proposed for biomedical device engineering. Interventions are justified based on an ethical position that considers the actions of designers themselves and not just the consequences of using a technology once it is deployed.

[40] The American Medical Association (AMA) Codes of Ethics identifies 9 Principles of Medical Ethics which describe the core ethical principles of the medical profession. This includes guidelines related to treatments and the use of technologies. For more information see: https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview.

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APPENDIX A. IRB MATERIALS

Values and Design of Novel Biomedical Technologies [Dissertation Project] Information Sheet

Project Overview
This dissertation project will focus on how research communities perceive and navigate various values when designing biomedical technologies. Specific emphasis is on technologies that are designed for use inside the body (e.g. synthetic tissue, therapeutic/diagnostic nanotechnologies). These technologies represent some of the most cutting-edge research happening at the intersection of medicine and engineering. The development of these novel biotechnologies is also happening at a time when publicly funded agencies (e.g. NSF, NIH) increasingly expect scientists to consider how their research outputs impact society. The goals of this study are to not only understand how individual scientific communities design biomedical technologies based on various values, but also how these communities communicate about and consider values during the design process of these technologies.

The principal researcher of this project is Beth Strickland Bloch, PhD Student, School of Information Sciences, University of Illinois, Urbana-Champaign. The Director of Research and Chair of the dissertation committee is Professor Peter Darch, School of Information Sciences, University of Illinois, Urbana-Champaign.

Research Questions
This research project will be guided by three broad research questions:

1. How do the values of biomedical engineers influence their design practices of novel biotechnologies?
2. How do biomedical engineers develop their values and what factors shape these values?
3. What strategies could biomedical engineers use to realize, discuss, and reflect upon values to better inform their design decisions?

Research Methods
This project will use qualitative social scientific research methods, including observation and interviews.

Observation
Once permission to conduct fieldwork has been secured by laboratory leader(s), the study begins by the researcher observing the actions and behaviors of scientists/researchers in their daily work environment (i.e. “the field”). Observation includes watching researchers at work in the laboratory or in their offices. It may also include attending group meetings or other activities where the technology in development is discussed. Once a fair amount of observation data is collected, the researcher will ask individual participants for permission to be interviewed.

Interviews
Participant interviews will happen on-site in effort to better understand the roles, responsibilities, experiences, and perspectives of each person. They will be asked questions about their background, their work, and decisions they make when carrying out their work. Clarifying questions about activities previously observed may also be asked of participants. Interviews are expected to last from 45-60 minutes and will be audio-recorded if permission to do so is given by the participant. Transcribed interviews will be returned to participants and they will be given the chance to amend or revise their comments in the interview. Participants may request that transcripts be destroyed at the end of the study, and they may also review audio recordings of their interview at any time.

Protecting Research Participants
Approval from the Institutional Review Board (IRB) at the University of Illinois, Urbana-Champaign, was given in November 2017 (#18309). The purpose of this approval is to ensure that the confidentiality and interests of the participants are protected.

The laboratory leader needs to give permission before any fieldwork can begin. Each individual present must also give permission to be observed or interviewed. Should any person elect not to participate in the study, their request to not be watched or questioned will be respected. The researcher will also fully respect the time and work commitments of each participant. The work of the lab will remain the priority at all times. All prospective participants will receive an information sheet about the study and will be given the opportunity to ask the researcher questions about what might be involved. No visual or audio recordings of the field will be recorded. The terms of any Non-Disclosure Agreements will also be honored.

Some participants will also be asked to be interviewed as a part of this study and may decline to do so for any reason. Those who agree will be asked to sign a consent form. Participants will also be able to specify restrictions on the use of the interview and interview transcripts. Participants may also elect to remain anonymous in any interview transcript or in reference to an information contained in the interview. If they request to remain anonymous, pseudonyms will be used for them and their affiliated group within all study related documents. Every effort will be made to ensure that any identifying information obtained in this study will remain confidential.

All audio recordings, interview transcripts, researcher notes, and other working documents will be securely stored. Paper items will be stored in a locked desk only accessible by the researcher. Digital items will be stored on a password-protected area of the University of Illinois server. Only the researcher will have access to this server area.

Anticipated Time Commitment & Start Date
The amount of time the researcher spends in the environment depends on what is approved by the laboratory leader(s). The ideal amount of time to study the XX Lab would be XX days a week for a duration of XX months. .

Anticipated Research Output
The research outputs of this project will include the production of a doctoral dissertation. Additionally, the findings of the study, including any recommendations for improving communication practices, will be shared with the laboratory through a research presentation and/or summary report.

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SOCIAL BEHAVIORAL RESEARCH CONSENT FORM

Research Information and Consent for Participation in Social Behavioral Research

Values and Design of Novel Biomedical Technologies

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principle Project Investigator: Beth Strickland Bloch, PhD Candidate – mestric2@illinois.edu
Advisor and Dissertation Committee Chair: Professor Peter Darch – ptdarch@illinois.edu
Department & Institution: School of Information Sciences, University of Illinois at Urbana-Champaign
Address and Contact Information: 501 E. Daniel St., Champaign, IL 61820
IRB Project: #18309

Why am I being asked?

You are being asked to be a subject in a research study about how researchers perceive and navigate various values when designing biomedical technologies. The goals of this study are to understand how scientific communities design various biomedical technologies based on various values, and how they communicate about these values with other members of the research community.

You have been asked to participate in the research because you are a member of a research group which designs a novel biomedical technology and your thoughts and opinions about how these biotechnologies are designed are important to this study.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Urbana-Champaign. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

What are the potential risks and discomforts?

Participation in the Values and Design of Novel Biomedical Technologies involves minimal risk to the subject, which means, to the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

Are there benefits to taking part in the research?

This study is not designed to benefit you directly. This study is designed to learn more about how values shape the design of novel biomedical technologies. The study results may be used to help other people in the future.

Will my study-related information be kept confidential?

Faculty, staff, students, and others with permission or authority to see your study information will maintain its confidentiality to the extent permitted and required by laws and university policies. The names or personal identifiers of participants will not be published or presented.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time.

The Researchers also have the right to stop your participation in this study without your consent if:

→ *They believe it is in your best interests;*
→ *You were to object to any future changes that may be made in the study plan;*

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 217-333-2670 or e-mail OPRS at irb@illinois.edu

If a University of Illinois Student

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIUC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

If a University of Illinois Employee

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at the University of Illinois at Urbana-Champaign. You will not be offered or receive any special consideration if you participate in this research.

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

_____ _____

Signature of Person Obtaining Consent Date (must be same as subject's)

_____

Printed Name of Person Obtaining Consent

APPENDIX B. INTERVIEW PROTOCOL

Interview Protocol
[Dissertation Project: Values and Design of Novel Biomedical Technologies]

Alias: _____ Date/Time:_____

Section I: Background & Current Projects

1. What is your educational background (e.g. types of degrees)?
   a. What motivated you to get _____ degree(s)?
   b. What type of courses have you taken as a part of your educational training?
   c. Have you taken any classes/workshops related: (ethics, social impacts, human factors)?
2. How would you describe what your laboratory studies?
   a. What type of research methods do people in your lab use (e.g. in vivo, in vitro, human)?
   b. Does your group collaborate with others (e.g. on-campus, different universities)?
   c. Does your group have any clinical/physician/healthcare collaborators?
   d. Which organizations currently (or previously) have provided funding for your group?

3. Would you please describe for me a current project that you're working on?
   a. What do your daily tasks look like?
   b. How did the initial project come about?
   c. Why was this project considered important to perform?
   d. What parts of the project look different now than originally intended?

Section II: Group Dynamics

1. Do members of your group have similar or different backgrounds?
   a. How are misunderstandings dealt with among members of your group?

2. Who is often thought of as the primary users of the technology (or method, or technique) being developed in your laboratory?

3. What type of meetings do members of your laboratory have on a regular basis?

Section III: Publishing, Commercialization & Funding

1. How is publishing discussed among group members?
   a. Which journals are usually the ones you group submits manuscripts to?
   b. How important is to you to get your names on publications before you graduate/leave?

2. Have you or anyone in your group been involved in a project that has resulted in a patent or commercial product?

3. Have you ever worked on any part of a funding application for yourself or for your group?
    a. Have any of these applications asked to address the potential social impacts of the projects being proposed?

Section IV: Identity & Discipline

1. Do you consider yourself someone who studies technology?

2. Would you describe yourself as more of a scientist or more of an engineer?

3. I once heard a biomedical engineering professor say: “It’s easier to teach an engineer biology than it is to teach a biologist engineering.” What do you think of that statement?

4. What type of work/project would you like to be doing next?
    a. What type of career path are hoping to pursue? Industry? Academia? Something else?

End Questions

1. Do you have any questions for me? Any other questions or comments?

2. Do you know of someone else in your laboratory who might be interested in speaking with me?

APPENDIX C. LIST OF NVIVO CODES

- Academia (81)
  - Institution (34)
  - Department (35)
- Biomedical Engineering (103)
  - Disciplinary Identity (57)
    - Engineer (105)
    - Scientist (84)
  - Political Identity (20)
  - Knowledge (33)
    - Problem Solving (22)
    - Shared Language (73)
    - Teach Bio vs. Eng (89)
  - Training (75)
- Biotechnology (7)
  - Cost (20)
  - Data (104)
  - Decisions (70)
  - Definitions (43)
  - Design (163)
    - Funding (16)
    - Health Need (45)
    - Novelty (39)
    - Physician (55)
  - End User (40)
  - Impact (32)
  - Motivations (85)
  - Stage of Development (120)
  - Type of Biotech (130)
- Clinical (67)
  - Samples (22)
- Collaborators (54)
  - Grants (15)
  - Physician (43)
- FDA (34)
- Funding (63)
  - Competitive 25)
  - Government (77)
  - Societal Impact (35)
- Industry (69)
- Intellectual Property (48)
- Laboratory Group (112)
  - Backgrounds (49)
  - Equipment & Space (64)
  - Hierarchy (37)
  - Meetings (60)
  - Research Projects (77)
  - Views of P.I. (105)
- Publications (66)
  - High Impact (28)
  - Process of (55)
  - Quantity (31)
  - Quality (17)
- Science (17)
  - Applied (48)
  - Basic (71)
  - Knowledge (20)
  - Modeling (48)
  - Practice (28)
  - Quantitative (18)
  - Visualization (6)
- Translational (81)
  - Start-Ups (27)
  - Tech Transfer (18)