Training the Responsible Conduct of Research and Design

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Recommended Citation
Goldberg, Jay R., "Training the Responsible Conduct of Research and Design" (2022). Biomedical Engineering Faculty Research and Publications. 669.
https://epublications.marquette.edu/bioengin_fac/669
Training the Responsible Conduct of Research and Design

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Abstract:
Students Supported by grants from the National Institutes of Health (NIH) are required to complete training in the responsible conduct of research (RCR). This training includes topics such as authorship, handling of data, reporting of results, maintaining confidentiality, and other topics related to the ethical and responsible conduct of research. It prepares students who are supported by NIH research grants for careers involving research.

The NIH R25 grant program titled “Multidisciplinary Team-Based Design Education to Create Biomedical Engineering Innovators” provides funding for BME design projects such as those found in senior capstone design courses. Students working on design projects supported by these grants are required to complete the RCR
training, even though they are not involved in research. For each of the last five years, 40–50 of my senior capstone design students who worked on projects supported by one of these grants were required to complete RCR training each year. For this reason, I was asked to help facilitate discussions of some of these topics with small groups of these students.

Most BME students around the country will eventually work for medical device companies during their careers. After the first year that I participated in the RCR training, I realized that some of the research topics covered in the training sessions were less relevant to students who did not plan to pursue careers in research. I felt that there were topics that would be more applicable to students planning to work in the medical device industry. For example, issues dealing with authorship of articles are not important to industry engineers since few of them will publish research articles in journals. However, issues dealing with intellectual property are highly relevant to industry engineers since many of them will submit patent applications for their inventions.

Engineers involved in new product development and design are often involved in research and development. Understanding and practicing the RCR is certainly applicable to research and development activities. However, for those students interested in pursuing careers in the medical device industry, additional topics could be added to the RCR training curriculum. Discussion of the rules for patents and inventorship, confidentiality, and the differences between companies and academic institutions regarding the expectations and goals of research, testing, and reporting of test results could be included in RCR training to better prepare BME students planning careers in the medical device industry for the responsible and ethical conduct of research and design.

Rules Regarding Patents and Inventorship
The rules for inventorship are much different than those for article authorship. Those who contribute test samples or provide specialized laboratory equipment may be included as authors of an article along with those who conducted the research, analyzed the data, and wrote the article. In contrast, U.S. patent law considers inventors to be those who make novel “inventive contributions” to an idea or design. Although building and/or testing prototypes or analyzing data are significant contributions to a project, they do not constitute inventive contributions and would not qualify one to be listed as an inventor in a patent application. Similarly, department managers, lab managers, department heads, and deans do not qualify as inventors simply because of their positions or for providing resources to a project team.

Goals of Research and Impact on Confidentiality and Protection of Intellectual Property
The goal of academic research is often to contribute to the body of knowledge. To accomplish this goal, researchers need to disseminate research findings, typically through public disclosures consisting of publications in journals and presentations at scientific and professional meetings. Academic career advancement often requires these activities. For these reasons, academic researchers have an incentive to share their work with others and contribute new knowledge to the field.

Industry research typically has a different goal. It is intended to either solve a problem for the company (e.g., reduce cost, improve a process or performance of materials) or develop technologies and devices that will result in commercializable products that address unmet customer needs. To leverage the competitive advantage provided by patents, industry research and development results are often kept confidential to protect intellectual property until patent applications have been submitted or a patent has issued. For these reasons, public disclosures of research results are often prohibited, and nondisclosure agreements are used to protect confidentiality during meetings with potential vendors, clinical investigators, and others prior to submitting a patent application.
Students need be aware of the rules regarding grace periods no matter which career path they take. In the United States, inventors have one year after a public disclosure to submit a patent application to avoid losing their patent rights. However, once an invention is publicly disclosed, inventors lose their patent rights in the European Union, and the invention becomes part of the public domain. This is one of the reasons why technology transfer offices at academic institutions discourage public disclosures of faculty research and inventions before a patent application is submitted.

Testing, Data Analysis, and Reporting of Results
In an academic setting, there are situations where researchers may be tempted to manipulate data or ignore or not report negative results. These are addressed in detail in RCR training sessions. In an industry setting there are some different pressures regarding testing and the reporting of test results. First, because delays in new product introductions can impact market share and revenue, project teams are under constant pressure to not only “get products out the door” but to also introduce them on time. Project managers and engineers may be pressured to skip certain tests or take shortcuts to save time. Second, if test results do not support claims of clinical safety and efficacy, engineers and scientists may be tempted to reject the “bad data” points, conclude that they are outliers, and ignore them. Third, if test results do not support certain performance claims, companies may choose to withhold them and not to report these “negative” results. Students need to be aware of these potential situations, recognize these behaviors as forms of unethical behavior, and know how to respond when witnessing unethical behavior in the workplace.

Current RCR Training could be expanded to address research and design topics for BME students. Discussion of the topics mentioned above need not be limited to students in the RCR curriculum. All students interested in academic or industry careers that involve research or new product development would benefit from these discussions. To best prepare our students for careers in these areas, they need to understand the responsible and ethical conduct of research and design, as well as be able to recognize and respond to unethical behavior they may observe in the work environment. Adding these discussions to RCR training sessions is a good first step, but adding them to the BME curriculum, either as part of the senior capstone design course or another course or seminar would allow all our students to benefit from training in the RCR and design.

A new design textbook of interest to BME design instructors and others will be available in June 2022. Biomedical Engineering Design (Elsevier), coauthored by Joe Tranquillo, Jay Goldberg, and Robert Allen, presents the design processes and practices used in academic and industry medical device design projects. The book begins with an overview of the design process, project management, and working on technical teams. Further chapters follow the general order of a design sequence in BME, from problem identification to validation and verification testing. The book can be used for first-year and sophomore design classes as well as senior capstone design courses and upper-level students. It includes in-depth discussions of detailed design, testing, standards, regulatory requirements and ethics. Final chapters summarize the various activities that industry engineers might be involved in to commercialize a medical device.

This book covers subject matter rarely addressed in other BME design texts, such as packaging design, testing in living systems, and sterilization methods. It provides instructive examples of how technical, marketing, regulatory, legal, and ethical requirements inform the design process. It includes numerous examples from both industry and academic design projects that highlight different ways to navigate the stages of design as well as document and communicate design decisions. The book provides comprehensive coverage of the design process, including methods for identifying unmet needs, applying design for “X,” and incorporating standards and design controls. It also discusses topics that prepare students for careers in medical device design or other related medical fields.
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Jay Goldberg is a professor of practice in biomedical engineering at Marquette University and the Medical College of Wisconsin, Milwaukee, WI. His research interests include development of new products in urology, orthopedics, GI, and dentistry. He received the B.S. degree in general engineering from the University of Illinois at Urbana-Champaign, IL, USA; the M.S. degree in bioengineering from the University of Michigan, Ann Arbor, MI, USA; and the master’s degree in engineering management and Ph.D. degree in biomedical engineering from Northwestern University, Evanston, IL, USA.