Crossing the line: When does the involvement of human subjects in testing of engineering capstone design projects require oversight by an IRB?

Ryan D Watts, Purdue University West Lafayette

Graduated from Purdue University in 2015 with a BS is Biomedical Engineering and currently pursuing medical training.

Dr. Andrew O. Brightman, Purdue University, West Lafayette (College of Engineering)

Andrew O. Brightman serves as Assistant Head for Academic Affairs and Associate Professor of Engineering Practice in the Weldon School of Biomedical Engineering. His research background is in cellular biochemistry, tissue engineering, and engineering ethics. He is committed to developing effective pedagogies for ethical reasoning and engineering design.

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Introduction

Engineering design projects in undergraduate capstone courses are increasing in sophistication and real-world relevance every year. More complex projects with real customer needs require significantly more advanced testing for design verification and validation that often will involve human subjects, especially for medically related devices. Currently there is limited policy information specifically addressing testing with human subjects in capstone engineering design courses, even in biomedical engineering. Most policies are regarding the more specific category of Human Subjects Research (HSR) and are not clear about when device testing in capstone courses crosses the line into HSR that would require Institutional Review Board (IRB) approval and oversight.

Many undergraduate engineering programs embed some form of ethics education into their capstone courses to prepare their graduates to have "an understanding of professional and ethical responsibility" (ABET 2012). However, the information about the ethics of testing with human subjects, including the students testing themselves, is less often addressed in terms of ethics in engineering design. The main ethics topics taught in engineering design courses at the senior level include professional responsibilities (e.g. ways to practice as an engineer in industry), research ethics (e.g. practices of responsible conduct of research), and codes of ethics for professional societies (e.g. NSPE, ASME, BMES). However, despite the fact that these important topics of professional ethics are being introduced in engineering design courses, they rarely touch on ethics of human testing. We hypothesize that this dearth of teaching in the classroom on this subject is due in large part to the lack of published information specifically addressing testing with humans in engineering design projects courses. Very little scholarly literature has been published about this important area of engineering ethics either. As well, professional ethical codes in engineering typically ignore student engineering design projects (Foot 2006) and likewise engineering design projects planning rarely address Human Subjects Research (Healey et al., 2013; Diaz & Nathans-Kelly, 2016).

This lack of clarity and lack of education for undergraduate engineers about testing human subjects in their design projects has multiple negative consequences. The first is that the engineering students and faculty members lack understanding as to when to involve appropriate oversight by regulatory entities such as the Institutional Review Board (IRB). Lack of clarity has consequences of putting the subjects of the testing at potential risk of harm and secondarily delaying the design project unnecessarily or changing the project all together (Healey et al., 2013). When there is lack of clarity as to whether a testing protocol needs review by the IRB there is often a lack of clarity about the safety of the protocol itself leading to potential harms for

the subjects. If students do discover (or it is determined by some other mechanism) that a review by the IRB is needed then the project is at risk of long delay while the review progresses through the appropriate official channels. Such delay can lead to frustration or failure of the project to meet timelines or a significant need for redesign of the project prototype or the project goals to circumvent that need for any testing with human subjects.

The second important consequence of the current lack of clarity around testing human subjects in undergraduate design courses is the resultant lack of preparation for future practice as an engineer in both research and practice. If one of the key goals of capstone design project courses in engineering is to prepare the engineering student for competency in real-world experiences then this lack of understanding, clarity, and thus competency around the ethics of testing human subjects has potential for future harm. While not all engineering disciplines, and thus not all engineers, will be engaged in testing with human subjects, many will need that competency. Particularly in the field of biomedical engineering, the likelihood of an engineering graduate to be involved at some level in design testing with human subjects is very high. Therefore, while the need for contextually-specific professional ethics training exists for many disciplines, the potential for harm from lack of proper training and understanding of Human Subjects Research (HSR) is particularly high in the healthcare industry (Kessel, 2014; Kohn et al., 2000; Levitz & Kamp, 2017; Maron & Hauser, 2007; Topol, 2004).

Thus in this Work-In-Progress paper we describe an initial analysis of the background literature to try to provide some clarity regarding HSR in engineering capstone student design courses and projects. The paper attempts to clarify the ethical guidelines associated with research and testing involving human subjects in capstone design courses and proposes a quick check decision-making process as a tool for determining if a project will require IRB oversight based on early stage design proposal documents.

Background Literature

Some reports in the published literature have approached the topic of human testing in undergraduate project courses from a research training focus rather than an engineering design focus. Still these studies can be illuminating and provide some foundational insights. For example, Pritchard (2001) helps tease out fundamental understandings of definitions of research and human subjects as found in the HHS's Common Rule (45CFR part 46, HHS 2017). Of particular interest are the ideas that in order to be designated as research according to the Common Rule the testing activity must have the intention to generate generalizable knowledge, whether or not it does so from the start, and that activities which are designed to serve as a step towards producing generalizable knowledge (e.g. pilot study, focus group) also can be considered as research and thus be required to have a protocol review and oversight. Bortolotti and Heinrichs (2007) extend these insights by attempting to more clearly delimit the concept of research and states:

> "Although the concept of research is important to delimit a class of activities which we might be morally obliged to promote, we observe that the class of activities which are regarded as subject to ethical regulation is not exhausted by research activities. We argue that, whether they be research or not, all the activities that are likely to affect the rights and interests of the individuals involved and impact on the rights and interests of other individuals raise ethical issues and might be in need of ethical regulation." [*Emphasis added*].

In addition to these insights, there has been considerable discussion and disagreement about labeling student projects as research or about whether these projects should be labeled as ethical or unethical. In an oft-cited paper in the literature Doyal (2004) addresses the ethical review of student projects in the UK. Doyal considers the fact that regulations in the UK appear to extend ethical oversight and review to student research projects at least in the healthcare field. Doyal proposes a potential role for a specialize form of oversight, student projects ethics committees (SPEC), that could give particular and nuanced reviews student projects, rather than the general research ethics review by university committees. Others, including Edwards (2009), have argued to the contrary, that there seems to be no good reason for treating student projects differently. They should be subject to the full review process as those projects led by more experienced scientists. Edwards states:

> "Educational objectives cannot be met without laying down standards of good science, whatever they may be. Weak science is unnecessary for educational purposes, and it is, in any case, unlikely to produce good researchers in the future."

Likewise, Foot (2006) has pointed out that there is no case for "accepting less stringent ethical criteria just because the researcher is a student." However, the argument for different review committees is not the same as a lesser review. The notion that some aspects of student projects will differ from qualified research projects brings up the question of "what constitutes as research?" as a way of ensuring equal application of rigorous standards of human subject research ethics.

While it is often the case that research performed with and by undergraduates will pose specific challenges to method and replication, Richman and Alexander (2006) argue that these challenges should require equal or more scrutiny by the research ethics community rather than being overlooked. The lack of significant impact of student projects does not mean there is a lack of significant risk or that their projects do not pose important ethical issues. Winder et al. (2007) support an even more stringent response to student projects to ensure ethical practice while in training. Wilkinson (2008) agrees with this stance and suggests that a more evolved system of review in response to these challenges could be beneficial to all ethics oversight. However, there is also acknowledgement that some "design projects" might not be qualified as research and thus might invoke a different decision about ethics review and oversight. Hack (2012) points out that goal of minimizing risk to all participants, including the students themselves, must remain a primary focus of determination of research and of need for ethical oversight. As well, the process

of ethical review, if it is transparent and proportionate (and efficient), by institutional review committees can be an important opportunity for education of students about ethics in real practice.

Some capstone design courses in engineering do include lessons regarding the ethics of research practices. Kramer et al. (2004) stress the necessity to take ethics courses as an engineer and also to integrate ethics education into capstone courses so that students know many implications of their projects. Richards et al. (2012) suggest that ethics education regarding the possible application of both animal as well as human testing that might be necessary to validate such design projects. When Human Subjects Research ethics is considered in capstone design courses, the ethics of students participating in the research themselves will likely arise.

Regarding current literature discussing IRB review of capstone courses, Blustein et al. (2004) references both Federal Regulations as well as the Belmont report to argue that research is defined by its intent and whether it is performed systematically. A project is designated as being research if the intent of the study is to contribute to generalizable knowledge. Again, the Common Rule definition of research is referenced in a discussion of regulation of a testing study depending on how systematically the testing is conducted. The authors point out that some capstone courses are done for the benefit of only a company or applicable institution, and not for the benefit of generalizable knowledge. When this is the case it supports an argument against IRB oversight because these studies are “for the client audience, and not for general consumption”. Another point made is that some capstone projects are not systematic, scientific, or protocol-driven, and instead are highly pragmatic, inherently "messy," non- protocol-driven, and subject to frequent revision. These observations drive forth the point that many capstone projects should be excluded from being considered research and thus would not indicate the necessity for IRB review.

IRB Guidelines and Information

In addition to published literature on the ethics of human subjects research IRB guidelines exist at each institution. Some universities also have implemented specific ethics committees for technology research that is not medically oriented but still requires human testing in order that guidelines for this specialized type of research could be established (Koepsell et al., 2014). There have been many IRB guidelines established for biomedical research as a whole, but there is a large gap between the level of regulation developed for clinical research as compared to engineering research (Monzon 2004). Munzner, et al. (2004) have suggested that IRB review strategies have changed from their roots as being intended “to be local and to interpret the degree of risk as the local community would perceive it”. They argue that this leaves too much room for interpretation by IRBs when it comes to larger population medical device trials, and that unique guidelines need to be set for these large population trials that apply to more than just a “local community” as was originally intended. Similarly, Whitney et al. (2012) argue that IRBs today might fail to protect certain “vulnerable” groups. This possibly could be applied to

students involved in research (Runeson 2003), particularly if they are doing the testing on themselves in capstone courses. The students could be considered at risk of coercion because they feel obligated to take part in testing when it is being supervised by a professor who is giving them a grade. Whether or not it is technically required for a course or design project, they will arguably feel more driven to participate in human trials in order to improve their performance with the professor. Students in capstone courses with human testing required could be at risk of coercion because although they may not technically be required to take part in the trials of their own design, it may be expected that their design be validated by the testing, and thus they may feel obligated to do it themselves.

When considering if human subjects testing done in capstone courses should be considered as Human Subjects Research in the first place, it is necessary to consider undergraduates' contributions to the research community and the perceptions of its validity. Brewer et al. (2012) describe how the use of undergraduate research data is lacking validity as there is a common focus on the experience and contribution from graduate students, and that exploitation of undergraduates as human subjects of research without proper data reporting does occur. Similarly, Antes et al. (2003) mention that lacking the reporting of undergraduate research data, due to the small size of testing populations, can be perceived as unethical and should be remedied. The perception of undergraduate research is important especially when it comes to defining what studies can be considered research. Much earlier, Edwards et al. (1997) made the notable point that many "underpowered" studies, including those of undergraduates, are consistently labeled unethical, and that recent data suggests that this status quo understanding is incorrect. Conversely, Gallagher et al. (2014) make a point that a study should not even be allowed until it is determined by an ethics review committee to be "of publishable quality" which would exclude many undergraduate design project studies.

It is necessary to define boundaries as they apply to what defines research and what cutoffs can be made between concepts such as ethics, science, and legality of research, and there is a need today for the definition of such to be accepted in the academic setting. Dawson & Yentis (2007) argued that the committees today reviewing research projects and trials might have two groups that evaluate based on science and ethics separately. While they argue that there is no real cutoff between the two and there should be a hybrid evaluation to better decide on what research should be taking place in the academic setting. Elena et al. (2010) mention that there is a growing disparity between ethical and legal considerations of biomedical research, and international guidelines for how universities conduct research while collaborating overseas need to be established.

There are many academic engineering programs that already include students in human testing as a curricular learning experience. For example, Trucco and Trucco (2011) in HP Labs have included students in the testing of their own man-powered flight designs. Additionally, students were included in empirical studies in software engineering education at Maryland University (Singer and Vinson, 2002), and Carver and colleagues describe in a publication how the trials

went, some ethical considerations of the study, and what they suggest could be done in future similar trials. The costs and benefits of student participation in human trials are extensively evaluated in regards to multiple stakeholders, a benefit for example being that it is less costly and can easily validate a hypothesis, while a cost for example being the questionable validity of the experiment if the students are previously informed on the study instead of being blind. Many ethical issues are noted as well, for instance that it is ethically questionable to include a student's performance in the trial in regards to their course evaluation. Overall, it is suggested in their publication that students be informed clearly and early on the goals, risks, and benefits of the study. Students can be motivated in a study without revealing the goal, and keeping the students and other project stakeholders informed on the outcome of the study is important to the ethical consent (Host et al. 2000).

Given this lack of clarity in the literature and IRB guidelines on what aspects of testing of human subjects in student design course projects needs ethical oversight by an IRB it is not surprising that there is significant confusion and frustration by student engineering design teams. In light of this situation we have set out to envision an efficient and effective way for engineering student design teams and their faculty mentors to determine if a testing project needs ethical oversight from IRB review and protocol approval.

Research Plan

We created a five-question quick evaluation tool for engineering design project teams to help determine if they need ethics review and testing protocol oversight by an IRB. The five questions are based on the definitions of human subjects and of research and are a risk-based tool that seeks to give some level of clarity for students and faculty mentors to decide early if they need to pursue review by their IRB. To assess the potential impact of the five-question quick evaluation tool, it was applied retrospectively to project design proposals (PDP) from two years of capstone design projects in a biomedical engineering program. PDPs are created in this program during the junior design preparation course. The project proposals are created at the end of months of idea generation, market analysis, and concept vetting using the design model of BioDesign (Stanford). PDPs are then used by capstone design faculty members at the end of the spring semester to determine which projects are appropriate and ready to go forward into senior-level capstone design in the following fall semester. Thus if the evaluation tool was effective at the PDP stage then the determination of a need for IRB oversight and approval could happen months before the design project was initiated and could obviate unnecessary delays, frustration, and potential harm due to lack of oversight. Comparison of the evaluations of the tool with PDP and the final DHFs for the same projects will be used to determine effectiveness of the five questions tool at early evaluation.

Five Questions:

1. **Are any humans included in the testing plan?**

2. **Is the data collected directly about the person(s) in any way?**
   (e.g. physical, demographic, capabilities, etc. including personal identification information; name, picture, age, SES, etc.)
3. **Is the data collection from testing / evaluation resulting in any type of tables or graphs?**
4. **Is there a plan to publish or present the results in any public format?**
5. **Is there any risk of harm to any persons in any way?**
   (If yes please describe the level of risk and type of harm)

Data Analysis: **Initial Results**

The results for the five-question analysis of PDP files are shown in Figure 1. This bar graph shows how many of the capstone design files answered "yes" to each of the five questions. The more questions indicated yes for a capstone design file PDP, the more likely it is that the according senior design project requires Human Subjects Research review and thus may need further approval upon its necessary testing in the future. It was found that question 3, asking if the project included tables and/or figures of data, had the most design files indicating a positive, "yes" response. Conversely, question 4, asking if the project team plans on publishing and /or presenting the data collected, had zero files indicating the answer was "yes". Overall, at least 21 projects out of the total 30 showed some evidence of necessity for seeking approval of Human Subjects Research. Further analysis of DHF files and the comparison between the studies will be reported at the conference.

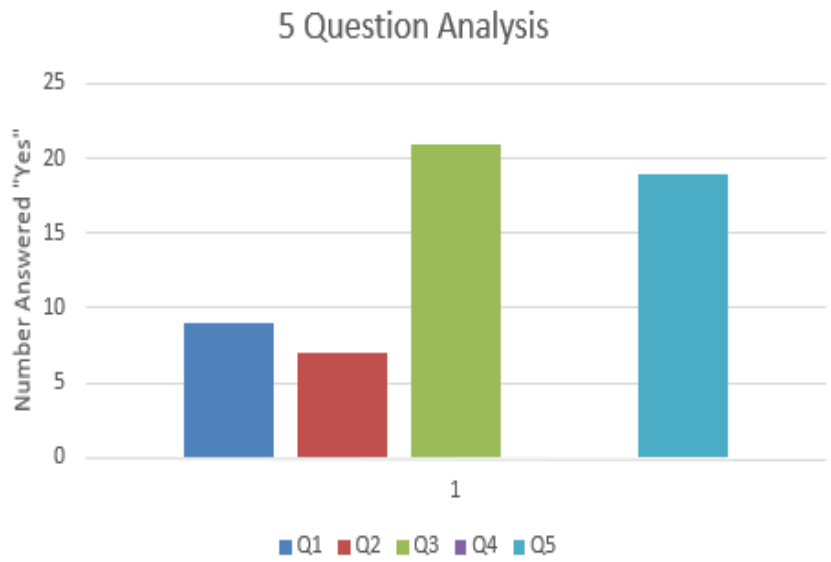

Figure 1: Five-question analysis of 30 capstone design projects

Furthermore, Figure 2 shows how many capstone design projects indicated "Yes" for up to 5 of the questions. This shows that only eight of thirty (30) of the design projects evaluated indicate

no positive responses at all and thus a very low likelihood of necessity for IRB review. However, no PDP indicated positive responses to all 5 questions thus showing the majority of projects had some level of ambiguity about the requirement for IRB review for their planned testing.

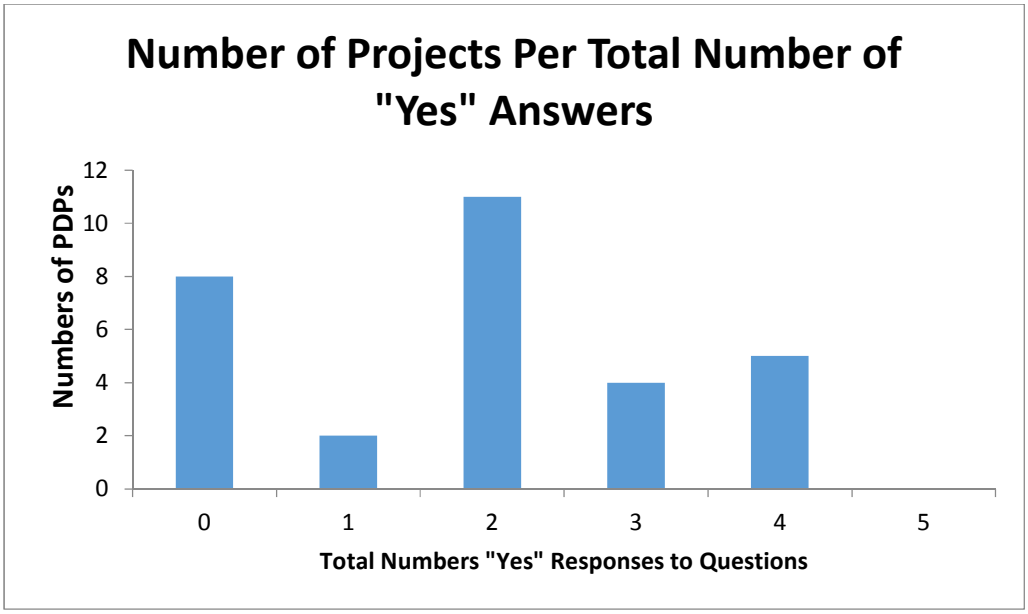

Figure 2: Histogram representing number of capstone design projects per total number of questions indicating “Yes”.

Discussion

It is very important for a project that will require Human Subjects Research approval for testing at some point in the future to receive this approval in the earliest stage possible. Often the protocol approval for human subjects testing will take much longer than a capstone course will last in terms of time allotted in a semester. If no testing can be done during the allotted time, then the project will be much less effective in proving to be a viable design in the industry upon its completion. Therefore, if IRB approval were to be acquired earlier, for instance in the summer before capstone design commences, it is likely that students would be able to start testing as soon as the design prototype was ready.

From the results above, it is seen that out of 30 projects, 9 say yes to question 1, 7 say yes to question 2, 21 say yes to question 3, 0 say yes to question 4, and 19 say yes to question 5. From a preliminary look at this data, it can be seen that many of the projects evaluated would likely require some form of review for approval for future Human Subjects Research in order to fulfill the requirements of project testing for validation and verification. The fact that 21 of the projects answered yes to question 3: *including tables and figures* and 19 answered yes to question 5: *testing plans possibly doing harm to human participants* suggests that the majority of projects in the capstone design course in biomedical engineering at this university are likely to require

protocol approval from the IRB to move forward with testing. Student teams can utilize this quick evaluation tool throughout the development of the project to help in finding that a project does or does not require IRB review as the project moves forward. This way the team can be proactive in determining for themselves if they will need to seek IRB approval for human subjects testing in the future. Once a team has determined for themselves that they might require IRB review, the faculty mentor can also utilize the quick evaluation tool to confirm the team's decision. If the faculty mentor agrees, based on the quick evaluation, that IRB approval will be required for further testing of the capstone design project, steps can be taken early on in the project's development to ensure that the protocol for Human Subjects Research would be approved in time for the testing to begin as soon as applicable.

Regarding the fact that none of the 30 PDPs indicated having a plan to publish and/or present data from the design project, there are several possible reasons for that outcome. The first would be that none of the project teams believed at the early stage that their project and/or testing would ever make it far enough to publish and present data. The second would be that the design teams could have concluded that IRB approval might be required before testing needed to begin and thus would delay the possibility for publication. The third possible reason for having no plan for publication was that none of these preliminary capstone design documents contained any specific questions about student plans to publish their testing data. Therefore, it cannot be directly concluded that students had no plans of presenting and publishing data, but due to preoccupation with other aspects of the assignment within these documents that they did not take this into consideration and they did not write about it. It could be concluded that students would more very likely to note plans to present and publish if PDPs assignments included specific inquiries about project publication outcomes. It can be further concluded that it would be helpful if capstone design documents included these inquiries on further project plans so that plans for human subjects research in the future can be more effectively elucidated and testing planned accordingly.

Conclusion

After five-question analysis of the 30 engineering capstone design team PDPs and studying the results, it can be concluded that the majority of these biomedical engineering capstone design projects have plans for human subjects testing in the future to some extent. If the testing is deemed to be Human Subjects Research and if IRB approval could be acquired at an earlier stage, it is likely that these design projects that require future human subjects research could be started as soon as needed in the capstone design course. Finally, preliminary capstone design files (PDPs) in the future should require more specific inquiries on plans of Human Subjects Research as well as presentation and publication of such data so that student teams and faculty mentors overseeing these projects can take steps toward IRB approval as early as possible. This will make future capstone design projects more efficient and successful as well as give engineering students a guide for ethical decisions regarding testing human subjects in their future design projects.

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References

Antes, G., & Chalmers, I. (2003). Under-reporting of clinical trials is unethical. *The Lancet*, *361*(9362), 978-979.

Blustein, J. (2004). Should capstone course activities undergo human subjects review?. *Journal of Policy Analysis and Management*, *23*(4), 921-927.

Bortolotti, L., & Heinrichs, B. (2007). Delimiting the concept of research: an ethical perspective. *Theoretical Medicine and Bioethics*, *28*(3), 157-179.

Brewer, G., Dewhurst, A. M., & Doran, D. (2012). Undergraduate Research Projects: practice and perceptions. *Psychology Learning & Teaching*, *11*(2), 208-217.

Dawson, A. J., & Yentis, S. M. (Mar 1 2007). Contesting the science/ethics distinction in the review of clinical research. *Journal of Medical Ethics*, vol. 33, pp. 165-167.

Diaz, C. S., & Nathans-Kelly, T. M. (2016). Whose idea is it anyway?: Students communicating innovative and entrepreneurial work and the quagmire of ownership at the university level. In *Professional Communication Conference (IPCC), 2016 IEEE International*, pp. 1-9.

Doyal, L. (2004). The ethical governance and regulation of student projects: a draft proposal. *Bulletin of Medical Ethics*, (203), pp. 8.

Elena, T., Daniela D., & Alexandru T. I. (2010). "Ethical and Legal Aspects in Biomedical Research Involving Human Beings," in *Advanced Technologies for Enhancing Quality of Life (AT-EQUAL)*, pp. 79-82.

Edwards, S. J. (2009) Student projects in medicine: a lesson in science and ethics. *Accountability in Research*, 16(6), pp. 285-306.

Foot, H. C. (2009). Student research and ethics. *Psychology Teaching Review*, 12(1), pp. 82-86.

Gallagher, C. T., McDonald, L. J. & McCormack, N. P. (2014). Undergraduate Research Involving Human Subjects Should not be Granted Ethical Approval Unless it is Likely to be of Publishable Quality. *HEC forum*, pp. 169-180.

Hack, C. J. (2012). Ethical Review of Undergraduate Student Research Projects: A Proportionate, Transparent and Efficient Process?. *Bioscience Education*, (pp. 19).

Harris, J. (2005). Scientific research is a moral duty. *Journal of Medical Ethics*, vol. 31, pp. 242-248.

Healey, M., Lannin, L., Stibbe, A., & Derounian, J. (2013). *Developing and enhancing undergraduate final-year projects and dissertations*. York: Higher Education Academy.

HHS (2017) 45CFR46 in *Federal Register,* 82, No.12: *https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf*

Kessel, M. (2014) Restoring the pharmaceutical industry's reputation. *Nature Biotechnology*, 32(10), pp. 983-990.

Koepsell, D., Brinkman, W. P., & Pont, S. (2014). Human Participants in Engineering Research: Notes from a Fledgling Ethics Committee. *Science and Engineering Ethics*, pp. 1-16.

Kramer, K. (2004). Partnering with industry to promote ethical business practices in a capstone design course. *Frontiers in Education*, 2004. FIE 2004. 34th Annual, pp. S3E-1-5 Vol. 3.

Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (2000). To err is human: Building a safer health system. *Washington, DC: National Academies Press*, pp. 1-8.

Levitz, J., & Kamp, J. (2017). Deadly medicine: A common surgery for women and the cancer it leaves behind. *The Wall Street Journal*, pp. 1-42.

Maron, B. J., & Hauser, R. G. (2007). Perspectives on the failure of pharmaceutical and medical device industries to fully protect public health interest. *The American Journal of Cardiology*, 100(1), pp. 147-151.

Monzon, J. E. (2004). A code of bioethics for promoting biomedical engineering," in *Engineering in Medicine and Biology Society*, IEMBS'04. 26th Annual International Conference of the IEEE, 2004, pp. 5202-5204.

Munzner, R. (2004). Regulatory issues-informed consent for a device investigation. *Engineering in Medicine and Biology Magazine*, IEEE, vol. 23, pp. 97-98.

Pritchard, I. A. (2001). Searching for "Research Involving Human Subjects": What Is Examined? What Is Exempt? What Is Exasperating?. *IRB*, pp. 5-13.

Richards, K. A., Brugnano, J. L., Pool, M. A., Sieving, A. L., Velasquez, J. D., Voytik-Harbin, S. L., & Rundell, A. E. (2012). Scaffolding and Assessing Professional Design Skills using an Active-learning Studio Style Classroom. In *American Society for Engineering Education*. American Society for Engineering Education.

Richman, K. A., & Alexander, L. B. (2006). Ethics and research with undergraduates. *Ethics and Education,* 1(2), pp. 163-175.

Rogers, D.A.; Ribeiro, P.F. (2004). Work in progress - ethics integrated into engineering courses. *Frontiers in Education*, 2004. 34th Annual vol., no., pp.S1E/22, S1E/23 Vol. 3, pp. 20-23.

Runeson, P. (2003). Using students as experiment subjects–an analysis on graduate and freshmen student data. *Proceedings of the 7th International Conference on Empirical Assessment in Software Engineering*. Keele University, UK, 2003, pp. 95-102.

Schwartz, L. B. (2002). The dilemma of bioengineering research on human subjects," in Engineering in Medicine and Biology. *24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference*, Proceedings of the Second Joint, 2002, pp. 2668-2669.

Singer, J., & Vinson, N. G. (2002). Ethical issues in empirical studies of software engineering. *IEEE Transactions on Software Engineering*, *28*(12), 1171-1180.

Höst, M., B. Regnell, and Wohlin, C. Using students as subjects—a comparative study of students and professionals in lead-time impact assessment. *Empirical Software Engineering*, vol. 5, pp. 201-214.

Edwards, S., Lilford,R., Braunholtz, D., & Jackson, J. (1997). Why "underpowered" trials are not necessarily unethical. *The Lancet*, vol. 350, pp. 804-807.

Topol, E. J. (2004). Failing the public health—rofecoxib, Merck, and the FDA. *New England Journal of Medicine*, *351*(17), 1707-1709.

Trucco, H.A., & Trucco M.Y. (2011). Novel aeronautical engineering student Project: developing ultra-light-weight aerial Vehicle design, fabrication and human powered Flight trial. *American Society for Engineering Education*, pp. 22.1105.1- 22.1105.11.

Whitney, S. N. (2012). The python's embrace: clinical research regulation by institutional review boards. *Pediatrics*, vol. 129, pp. 576-578.

Wilkinson, M. (2008). Ethical review of undergraduate student research in the NHS: evolution of the system could benefit us all. *Journal of Medical Ethics*, 34 (9), pp. e19-e19.

Winder, B., Brunsden, V., & Farnsworth, B. (2007). Student research and ethics: contributing to the debate. *Psychology Teaching Review*, 13(1), pp. 48-50.