# A JOINT-VENTURE APPROACH IN TEACHING STUDENTS HOW TO RECOGNIZE AND ANALYZE ETHICS

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WORCESTER POLYTECHNIC INSTITUTE

By

Xavier Jackson, Zachary Jasensky, Vivian Liang, Melvin Moore, and Jake Rogers

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Submitted to

Professor Kristen L. Billiar, PhD

Professor Geoffrey Pfeifer, PhD

Biomedical Engineering Department
Humanities & Arts Department

**Abstract**

Educating engineering students on how to identify and navigate ethical situations can increase their awareness of and ability to analyze ethical issues they will encounter in their professional lives. Many engineering programs lack a systematic incorporation of ethics into their curricula, which may leave students without an appreciation of the significance of ethics in everyday engineering decisions. The goal of this project is to develop a system of ethics modules that can be efficiently incorporated into engineering courses. Several methods of teaching ethics were assessed in a sophomore-level biomechanics class, in which 80% of students felt they learned the most from a joint-venture method over alternative methods. The blended joint-venture module incorporates an ethics professional as a guest lecturer who exposes students to different tools to understand professional and ethical responsibilities. Joint-venture modules, customized to course content, were then piloted in three biomedical engineering courses at the freshman, sophomore, and senior level. The professors indicate that the ethics analyses are easy to incorporate into their curriculum without distracting from the engineering content, and 90.5% of the participating students agreed that the ethics guest lecture was helpful in comprehending the ethical material. With further studies, a more efficient and easy-to-use ethics program may be integrated into current engineering curricula. Engineering professors may be more prone to include such an implementation of ethics into their classes, and as a result may further promote the ethical education of students.

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**Authorship Page**

Each student contributed equally to this Interactive Qualifying Project.

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**Executive Summary**

**Introduction:** Engineers design, build, and develop products and processes that are used to improve people's lives. Decisions are often made that can compromise the safety and effectiveness of a design due to reducing cost or increasing the ease of manufacturing, putting lives at risk. Currently, professional ethics have not been sufficiently covered in engineering curricula. Students have reported that they experience little to no ethical content as part of their undergraduate studies. Due to the lack of engineering ethics incorporated into the classroom, students may pass through their undergraduate career being completely unaware of the importance of day-to-day decisions made in the field. This project is focused towards creating an easy-to-use, versatile system of ethics modules for the biomedical curriculum that will allow students to identify and navigate ethical situations. The modules will incorporate a joint-venture approach, bringing ethics professors into the classroom in order engage students in ethical dialogue through guest lectures and guided discussion to better prepare students for ethical decision making in their professional lives.

**Methodology:** Three methods of teaching ethics were implemented in a sophomore level biomechanics course as a preliminary study to determine the preferred method of ethical teaching. The joint-venture approach was met with favorable reviews, and a module system was developed centered around the joint-venture concept. To ensure the exposure of students to various ethical analyses tools, the modules consisted of a case study, a point/counterpoint assignment, a guest lecture, and a heuristics analysis. The modules were then incorporated into three pilot BME courses, with the difficulty of the case study adjusted to account for the varying class levels (freshman, sophomore, and senior). To monitor the ethical impact of the module on participating students, a survey on moral efficacy was given before the course and after the

course ended. The self-reported ratings were then evaluated with a t-test and power analysis. Interviews with the engineering and ethics professors were conducted after the modules ended to gather feedback and suggestions. Perceived student opinion on the effectiveness of the module were also gathered to help improve future implementations of the ethics module.

**Results:** In the preliminary study, the majority of students showed a preference for a joint-venture style of teaching ethics. The ethics guest lecturer and engineering professor also indicated that the amount of time required for both parties in coordinating guest lectures and presenting material was easy to manage. A formal module was then developed and implemented into three other BME courses as a pilot study. Overall, feedback showed that the modules increased student confidence in identifying and navigating ethical situations. The majority of the participating students found the guest lecture helpful in understanding the case study and explaining the purpose of the assignments, and most students participated in the module assignments for course credit. Of the participating students, 89.4% indicated that the ethics module did not distract from the engineering content, and 70.6% of the students would consider taking a full course dedicated to ethics. A large part of the student body, 90.6%, felt that they would know how to identify, analyze, and handle an ethical situation if one arose in the workforce, demonstrating the positive overall effect after a single module.

**Discussion:** The joint-venture approach takes into account that engineering faculty may not have enough background to teach ethics well, and philosophy professors may not have enough engineering experience to relate ethics with engineering. Having an expert in ethics come in to lead a discussion not only allows for students to gain more ethical exposure, but also allows the engineering professor to gain a sense of how to incorporate ethics into the curriculum. Overall, the joint-venture modules in teaching ethics were received with positive feedback from the students and professors. Student opinion indicated that the developed module successfully exposed them to situations with ethical components and helped to improve their ability to handle these situations. From the moral efficacy surveys, small increases in confidence were noted as a general trend from partaking in the module, but the changes were not statistically significant in any of the courses. We do not believe that these statistical findings mean that the module was ineffective, as a large change in a student's ethical reasoning skills cannot be expected from undertaking a single ethics module. With a larger population of students, longer study duration, and more in-depth modules, there could be a significant change in students' ethical education. Our results indicate that the ethics modules from this study are a good start to exposing students to ethics and broadening their mindset. However, in order to fully educate the students on ethical values, a more in-depth component needs to be considered.

**Conclusion:** There is a lack of ethics incorporated into engineering courses, which may leave students unaware of the importance of day-to-day decisions made in the field. A simple, versatile module was developed to increase ethical exposure and teach students how to identify and navigate ethical situations in the context of their technical coursework. Our study incorporated ethics modules into three classes, with overall positive results. Students indicated that they were more open to ethics-based lessons, and professors in both the biomedical engineering (BME) and philosophy departments agreed that the modules were effective in exposing students to potential ethical situations they may experience in a professional setting.

**Recommendations:** While the ethics modules did show successful results, the implementation of the modules requires refinement before success at a department-wide level. There is a lack of an intermediary between the BME faculty and ethics guest lecturers from the Humanities & Arts department. Future iterations would require a more direct method of contact to allow for better communication. Work also needs to be done to synchronize the modules on a broader scale if it is to be implemented across the curriculum in order to prevent any unnecessary repetitive exposure of material to the students. Organizing the modules to interact accordingly would also allow for a more complete exposure of the ethics material to students which would gradually introduce more complex materials to work with. If there was interest in expanding this study to include other institutions, modifications would have to be made to allow the module to work with different academic schedules other institutions may have. There are some confounding factors in the analysis, including the maturity of the students (there is a freshman, sophomore, and a senior class), and also the other courses students are enrolled in. For this reason, the case studies used in each class should remain different to limit repetition and retain student interest. If an across-the-curriculum approach is to succeed, the students will need to acquire some background in ethical theory and the reasons behind ethical thinking in the freshman and sophomore BME courses. Higher-level courses will have less time to focus on ethics, although some form of ethical exposure is still important to remind the students of their ethical responsibilities and aid them in identifying and handling ethical situations.

# I. <u>Introduction</u>

As engineering and its various subfields continue to advance, so must the education of engineers. Ethics is the moral code that dictates a person or group's behavior and how they would react to certain environments and situations, playing a fundamental role in a person's day-to-day decision making. Engineering curricula typically focus on manipulating technical aspects of a system to obtain a desired performance. However, since class time is dedicated to teaching students about engineering concepts, little time is used to address ethical decision-making in the engineering field.

Professional ethics has not been sufficiently covered in engineering curricula (Zandvoort, 2000). Current studies indicate that engineering curricula do not emphasize exposing students to engineering ethics (Herkert, 2000). Recent ABET reports show that only a few of the BME courses offered in most university level curricula provide any exposure to engineering ethics in class (ABET, 2012). The Biomedical Engineering program at Worcester Polytechnic Institute is no exception to this revelation. Recent ABET reports show that only a few of the BME courses offered at Worcester Polytechnic Institute (WPI) provide any exposure to engineering ethics in class (ABET, 2012). Across the curriculum, students have reported that they encounter little to no ethical content as part of their undergraduate studies. There is a lack of ethics incorporated into engineering courses, which may leave students unaware of the importance of day-to-day decisions made in the field.

In 1999, it was determined that nearly 70% of ABET-accredited institutions did not have an ethics-related course requirement for students in engineering (Stephan, 1999). Of the remaining schools that did have some form of an ethical requirement, over half of the institutions only offered courses in the humanities areas that did not focus on ethics in engineering. In 2007, research was conducted to determine whether new graduate engineering students were exposed to enough ethics as undergraduates. Each student took a multiple choice exam on responsible conduct of research. Results showed that student perception of ethical responsibilities had a low baseline, with a mean of 59.5% (Heitman, 2007). It was determined that new biomedical engineering graduate students had gaps in their core knowledge regarding ethical conduct of research. In order to create more ethically conscious students, many schools have added an ethics class to their engineering major requirements (Lynch, 1997). However, experts at Stanford largely agree that taking an ethics course will not make the student a more ethically aware individual (Speaking of Teaching, 1994). Modifying a major's requirements is a long, tedious process, and there are conflicting reports on how effective an ethics requirement is in creating more ethically conscious students. Studies have shown that by simply introducing ethical discussion into class, students are encouraged to engage in ethical dialogue, clarify their own values and commitments, and recognize potential ethical issues. While some schools add an ethics course requirement, others supplement engineering course syllabi with ethics components (Lynch, 1997). Using this method, the engineering professor gives a lecture on ethics using case studies as a means of engaging students in discussion.

This project is focused towards creating an easy-to-use, versatile system of ethics modules for the biomedical engineering curriculum at WPI that will allow students to identify and navigate ethical scenarios. The ethics modules will use case studies to allow students to become more engaged in the process of recognizing and apprehending ethics issues (Plemmons, 2008). The team's theory is that an interactive discussion with an expert in ethics, along with engaging case studies and assignments, will allow the students to become more aware of ethics in professional life, as well as how to handle them (Mance, 2007). The project will implement developed ethics modules into three BME courses to assess student interest in the team’s method of implementing ethics material into the various course curricula.

## II. Literature Review/Background

### 2.1 Importance of ethics

Ethical behavior is defined by fairness, honesty, and equality in professional, academic, and societal interactions (Wood, 2003). Experts at Stanford unanimously agree that one cannot expect a single class to make students more ethical. What teaching ethics can do, however, is allow students to confidently engage in ethical dialogue, clarify their own values and commitments, and view issues more tolerantly. The teaching of ethics also helps students become more comfortable talking about and debating their viewpoints on ethical matters, thus allowing them to engage an ethical problem correctly (Tripathy, 2013).

Engineers have a professional responsibility not only to their products, but to their clients and the general public (Herkert, 2000). The engineered products are developed to be safe and useful, and any adverse effects are the responsibility of the engineer. The professional responsibilities of an engineer include public safety, informed risk and consent, environmental welfare, loyalty, whistleblowing, and many others (Martin, 1996). Exposing students to engineering ethics will allow for them to better handle situations where ethical dilemmas may arise, and give the students the tools and means necessary for overcoming the ethical challenge. ABET accreditation in 2009 states that new engineers must demonstrate an “understanding of professional and ethical responsibility” (Mance 2007).

### 2.2 Inadequacy of teaching ethics in engineering

In 1999, it was determined that nearly 70% of ABET-accredited institutions did not have an ethics-related course requirement for students in engineering (Stephan, 1999). Of the schools that did have some form of an ethical requirement, over half of the institutions only offered courses in the philosophy or humanities areas, so engineering ethics is not necessarily sufficiently covered. In 2007, research was conducted to determine whether new graduate engineering students were exposed to enough ethics as an undergraduate. Each student took a multiple choice exam on responsible conduct of research. Results showed that student understanding of ethical responsibilities had a low baseline, with a mean of 59.5% (Heitman, 2007). It was concluded that new biomedical graduate students had gaps in their core knowledge regarding ethical conduct of research.

Another issue in teaching ethics in engineering curriculum is the fact that engineering professors may not feel comfortable with teaching ethics. Engineering professors spend the majority of their time studying different aspects of engineering, and may not feel familiar with the intricacies involved in ethics. There are also time constraints many professors face with peer reviews and research proposals. Professors simply do not have enough time to invest in a background in ethics (Eisen, 2002). Before student receptiveness can be measured and assessed, there needs to be a standard level of ethics knowledge attained by the professors in order for the students to learn from them. Introducing ethics modules into an engineering curriculum can only be effective if the teachers are prepared and capable in teaching ethics (Newberry, 2004).

In addition, professors interested in teaching ethics need to determine how and where an ethics course would fit into an already established engineering curriculum. The two main options are a stand-alone ethics course requirement or the integration of an ethics module into the original engineering curriculum. Both methods have advantages and disadvantages. The stand-alone course may not be as relevant to the specific issues each branch of engineering will take, since it will be a broader and general ethics course. An ethics across the curriculum strategy can remain relevant to engineering material, but at the cost of having to remove pertinent information from courses to find time for ethics lectures. Removing small amounts of time from each core course for ethics may have an overall impact on the students' engineering knowledge. However, incorporating another requirement to an already condensed schedule will make it difficult to obtain support for the ethics stand-alone course. The resources involved to create a stand-alone ethics course for an entire engineering department are also problematic, as they may need to hire additional teachers to lead the classes (Eisen, 2002).

### 2.3 Strategies of teaching engineering ethics (department level)

In biomedical engineering there are various types of ethics to take into consideration. A comprehensive ethics curricula would need to cover the fundamentals of ethics, research ethics, professional ethics (including the ethics that govern an engineer's behavior and the ethics governing a medical professional's actions), and social ethics (Monzon, 1999). To correctly and comprehensively teach all the subjects that biomedical ethics entails, a class would require professionals and specialists from several fields who are also qualified to correctly teach ethics. Ethicists, field engineers, physicians, and medical researchers are all professionals that can comprehensively teach biomedical ethics. Once the materials for teaching ethics is determined, the method of effectively relaying the material can be decided and ethics can be incorporated into an existing curriculum.

In a broad sense, there are three strategies of incorporating ethics into a curriculum: the across-the-curriculum model, stand-alone courses, and the joint-venture approach (Li, 2012). Teaching across the curriculum integrates ethics into the core courses of a program by having an integral component in all the engineering courses. Professors would incorporate ethics discussion and lectures into their syllabus, making the ethics component relevant to the individual courses. There should be graded assignments which are included into the final course grade (Weil, 2003).

An advantage of this approach is the involvement of the professor in the ethics teachings, demonstrating that ethics is integrated into engineering, and not just a small side component (Cruz, 2003). However, most engineering faculty do not have the necessary background to teach ethics effectively, and therefore may not feel comfortable with the idea of lecturing unfamiliar information. Since most institutions do not offer any compensation for attending workshops and learning the ethical requisites, most engineering professors simply do not incorporate an ethics component in their class (Newberry, 2004). In order for the across the curriculum approach to be efficient, faculty should be given a background in ethics, and should relate their own work to ethical applications to set an example for students.

A stand-alone course would be a class dedicated entirely to ethics. These are often offered in philosophy or other humanities programs, and typically are not taught by engineering professors. The engineering curriculum in question, in this case biomedical engineering, would add an additional ethics requirement to its curriculum. While a stand-alone course requirement could provide full emphasis and exposure to engineering ethics, it may give the impression that ethics courses are peripheral to engineering courses (Newberry, 2004). Another potential problem with making an ethics course a requirement is overcrowding a student’s schedule. Engineering students generally already have a busy course load, and adding another requirement would be stressful and perhaps discouraging. It is important that students are engaged and open to ethical ideas (Lynch, 1997).

The joint-venture approach takes into account that engineering faculty may not have enough background to teach ethics well, and philosophy professors may not have enough engineering experience to relate ethics with engineering. A joint-venture class would be taught by professors from different disciplines to expose the students to a diverse array of teachings, fully incorporating both the engineering component and an ethical component from experts (Graber, 2006). The diversity of the input from the faculty allows for many fields of expertise to be covered, inputting both engineering material and ethical material. The professors would divide the time evenly, although the problem of limited time may arise. By splitting the course in such a way, lecture time for each professor is cut drastically. The extensity of material may be brought into question. Another issue with this teaching model is the willingness of professors to participate (Li, 2012). A joint-venture course requires a considerable amount of coordination and effort.

### 2.4 Methods of teaching ethics (class level)

There are a variety of ways to teach ethics in a class, the most popular method being case studies (Lynch, 1997). Case studies are designed to expose readers to real-life issues that do not have an obvious solution. A lecture based on a case study would require critical analysis and discussion to expose students to new perspectives and ways of thinking. Case studies are a method to practice ethical decision making, and it needs to be emphasized that they are used as a process. By exposing students to ethical tools, students will be able to take their knowledge and apply it in their careers when confronted with moral grey areas. Part of the analysis process involves answering questions like who are the affected parties and what are their interests? Were the actions taken by the parties ethically acceptable and would you take that course of action? What actions could have avoided the conflict? This logical system aims to guide the student in determining the problems present, the actions that caused the problem, and who the actions favor. This way the student can try to work their way through and try to determine what would have been the proper actions to take in the situation (Plemmons, 2008). While case studies are a good way to teach ethics, it should not be the only means of ethical instruction (Haws, 2004).

Other methods an instructor can utilize to teach ethics include codes of ethics, simulation and role play, guest lecture, and point-counterpoint assessments (Newberry, 2004; Lynch, 1997; Li, 2012). The purpose of the guest lecture is to have a lecturer with more authority in ethics than the engineering professor to bring real world experience into a classroom and help the students understand what they are being taught. Professors who have studied engineering for the majority of their career do not qualify as an expert in ethics. Supplementing an engineering professor's lectures with an ethics professor's material can expose the students to ethics while still incorporating the necessary material into a curriculum. Students have a perceived sense of expertise from the professors, and will take the teachings from the respective instructors more seriously. A disadvantage to guest lectures, however, is the need for relevance between what the guest lecturer is presenting and the area of study of the class they are presenting to. For example, a guest lecture regarding the ethics in decision making in stock trading would not be well received in a biomedical engineering course, as there is no relevance to what the students are studying or what they wish to pursue as a career (Plemmons, 2008).

Role play is used to make ethical dilemmas more realistic. Instead of listening to a professor lecture about ethics, role playing allows the student to assume the role of a character and rationalize their actions and motives. When students take roles that oppose their personal opinion, it can be used to broaden their thoughts and see issues from alternative perspectives, similar to the point/counterpoint method. A role play activity is implemented by dividing the class into groups which are then assigned to create and act out a script. The script provides background information and starting points for the roles to be played, and the groups must clarify and explain their positions and approaches to each topic. Then, the scripts are given to different groups who must now carry out the role play. The disadvantage to this exercise is that each group will need a different script to plan out, which takes a considerable amount of time and coordination. It may not be feasible with the short time available in a single lecture, and it would also take a significant portion of class time to work properly (Plemmons, 2008).

Point-counterpoint assessments can be used with case studies to force the students to view both sides of an ethical dilemma, emphasizing the fact that ethics is not black and white, and in fact have many grey areas. There is no single best method to teach ethics. Instead, a variety of methods is encouraged. The point/counterpoint assignment shares some similarity with role playing in that it may encourage students to attempt to rationalize actions or behaviors that they would not normally present (Mance, 2007). An expanded perspective will help the students in the future when working with those with different views. Exposure to various methods of ethical teachings will allow for more ethical distribution and points of views, letting students gain more insight in the field of engineering ethics (Haws, 2004).

Reviewing ethical codes of conduct may give students an appreciation of moral theories, and encourages further exploration of ethics (Wood, 2003). Ethical codes are used to help a business or organization map out explicitly what is right and wrong within their profession. This reduces the moral grey areas that are present when novel situations occur as the rules and responsibilities are clearly defined. However, even with codes of conduct there has been no significant correlation to improving the behavior of individuals in industry (Adams, 2001).

Another popular method of ethical teaching is using heuristics, or analysis methods. Heuristics incorporates a process in which students can begin with identifying the ethical dilemma, follow steps to identify and analyze the issue, and eventually find a solution for the dilemma (Weil, 2002). It is an interactive process that engages the problem solving skills of the student, which can be seen as relevant to engineering, a problem solving occupation. No matter which methods or combinations of methods are used, it is agreed that interactive discussions play a vital role in ethical teaching. Discussions make the lesson communal and affect the students on a more personal level, forcing them to defend arguments and confer thoughts (Mance, 2007).

### 2.5 Constraints in implementing ethics into current curricula

The main constraint in implementing ethics into current curricula is that there is not enough time to properly introduce ethics into the syllabus while still covering the vast technical aspects of the course. Since there is little to no time to correctly address ethics, many professors either briefly touch on the subject or opt out of teaching it entirely (Eisen, 2002). Many of the classes dedicated to thoroughly teaching ethics are avoided by students as well, due to the lack of perceived importance (Herkert, 2006). Another issue in incorporating ethics into a curriculum is that there is no concrete way to evaluate a person's ethical behavior as ethics itself is not concrete. Ethics is not the decision of whether something is right or wrong, but the process by which an individual determined whether something is right or wrong.

### 2.6 ABET-accredited courses for ethics in BME curriculum at WPI

The IQP team reached out to some professors who already incorporate ethics into their BME classes. Professor Ambady teaches the biomedical physiology and engineering course, which is ABET-accredited for "an understanding of professional and ethical responsibilities" (ABET, 2012). The professor dedicates a full lecture towards the end of the course to discussing ethics in clinical trials and research, and a quiz and assignment are given as a form of evaluation. Professor Ambady focuses more on ethics in patient consent and covering liabilities than ethical professionalism. Another course that is ABET-accredited in ethics is the design course BME 3300, which every BME student is required to take. In BME design, a guest lecture is given on the importance of ethics and a component of a quiz is dedicated to the ethics lecture. In both

ABET-accredited courses, at least one full lecture (50 minutes) is dedicated to ethics, and an evaluation is implemented.

**2.7 Potential solutions**

Potential solutions for implementing ethics include having students read specific case studies that are tailored to their major and then developing point-counterpoint arguments to those studies, and having professional ethics professors give guest lectures on ethical situations the students may soon find themselves experiencing later on in their prospective careers. The team explored the various ways in which other institutions tried to solve the gap in ethical education for engineering students.

In the 1970s, the National Science Foundation and the National Endowment for the Humanities supported a project that brought engineers and philosophers together at the Rensselaer Polytechnic Institute's Center for the Study of Human Dimensions of Science and Technology and the Center for the Study of Ethics in the Professions at Illinois Institute of Technology. This led to introduction of engineering ethics. The ethics curriculum that was started in the engineering department at Mississippi State began after a request to an academic affairs subcommittee (Weil, 1985).

Stanford's engineering department requires a Technology in Society course to be taken by all students and Cornell University also offers a course in engineering ethics. The best programs have implemented stand-alone courses and ethics across the curriculum over time. The stand-alone course serves to give a general introduction to ethics, while incorporating ethics across curriculum allows students to relate engineering back to the stand-alone course, bridging the divide between engineering and ethics (Lynch, 1997). Mississippi State University introduced ethics into the engineering curriculum by an academic committee. The committee helped launch an ethics course in addition to modules of ethics content in courses throughout the engineering department (Lynch, 1997). The main pattern expressed by the Lynch paper is the best method is to have an introductory ethics course for engineering students. Then, introduce more specific and relevant ethics examples as they further their education.

The proposed solution to the gap in engineering ethics is to create an across-the-curriculum ethics module with guest lectures so ethics professors can use their expertise to show the value of ethics, and the engineering professors can use their expertise to relate ethics to engineering. This will make up for the engineering professors' lack of expertise in ethics while keeping the topics relevant to the engineering course (Graber, 2006). There will be a reduction in the amount of time that the engineering professor can devote to teaching engineering, but we feel that this disadvantage is outweighed by the benefits of exposing undergraduate students to ethics so they can be more ethically responsible when they enter their professional industry (Graber, 2006).

# III. Methodology

## 3.1 Restatement of goal

This project is focused towards creating an easy-to-use, versatile system of ethics course modules for the biomedical engineering curriculum at WPI that will allow students to identify and navigate ethical scenarios. The ethics modules will use case studies to allow students to become more engaged in the process of recognizing and processing ethics issues (Plemmons, 2008). The theory is that an interactive discussion with an expert in ethics, along with engaging case studies, will allow the students to become more aware of ethics in professional life, and how to handle them (Mance, 2007). The project team will implement ethics modules into three pilot BME courses at WPI to assess student interest in the developed method of implementing ethics material into the biomedical engineering curriculum as a whole.

## 3.2 Preliminary study

For a preliminary study, initial data were collected using an introductory biomechanics class (BME 2511) taught by Professor Billiar. The study was done to gather feedback from students regarding the deliberate ethics exposure throughout the course. Data from the students allowed the IQP team to get a sense of how comfortable the students were towards ethical thinking, which method of exposure they preferred, and from which method they felt they retained the most.

Three methods were used to evaluate the preferred method of teaching ethics from both the students and the professor. For the first method, there was an ethics case study and discussion led by Professor Billiar, who has no extensive training in teaching ethics. In the second method, students were given a brief point-counterpoint assignment based on a different case study presented in class. The assignment consisted of reading the case study regarding experimentation on human subjects, and writing two paragraphs presenting an argument for and against the study. For the final lecture, Professor Pfeifer, an ethics professor, came in as a guest lecturer for half the class period to discuss a case study regarding animal testing. For all three lectures, the students were required to read the article ahead of time and answer a question to verify reading.

The first method of teaching formed the control on which the effectiveness of other methods was based. The lecture conducted by Professor Billiar consisted of a simple case study and discussion, where the professor presented a case study in class and tried to engage the students in a discussion. However, only a small percentage of the class participated in the discussion. Since students were not required to submit any responses, the only metric for student engagement is the reported percentage of active students in the discussion from the professor. The professor indicated that only a few students engaged in discussion, and for the most part, it was similar to a regular lecture with him speaking and the students listening, with no active participation.

The basis of the point-counterpoint lesson included a basic presentation on how to form point/counterpoint arguments given by the project team and an assigned short case-study. The point/counterpoint assignment was expected to be approximately two paragraphs in length with the first paragraph defending the student's views, and the second defending the views opposing their own. It was expected that this activity would help the students in understanding the issues at hand comprehensively (Brunner, 2011). The professor assigned the point-counterpoint assignment as a homework question. After the homework assignments were submitted, the professor and TA for the BME 2511 class separated the point/counterpoint questions and gave the data to the IQP team for processing. The purpose of the assignment was to engage students in thinking alternatively, and hopefully allow students to realize that there are no right or wrong answers. It is important to understand that behind every professional decision are valid reasons, and when entering the work field, students will need to reflect on the outcomes of their choices. Credit was given if students attempted the assignment and supported their arguments.

For the final evaluation, students were required to read a short article on animal testing to prepare for a guest lecture from an ethics expert. A short questionnaire was given to verify the students had done the reading, using the Blackboard myWPI system. Professor Pfeifer who specializes in ethics, then gave a 25-minute discussion regarding the basis of ethics and the ethical dilemmas in the reading. The students were then given post-lecture questions to evaluate their thoughts on the lecture and whether their positions regarding animal experimentation had changed. The questions regarding the student's opinions can be found in Appendix A.

The class was surveyed after the last ethics lecture to assess which of the three methods the students preferred and learned the most from, as well as additional information the students may have had to offer. The survey used can be found in Appendix A. Input from the ethics and engineering professors allowed the IQP team to determine which method was easiest for both professors. From the responses, it was determined that the students preferred the guest lecture and discussion. The engineering professor also preferred the guest lecture, as it was the least time consuming and relieved any discomfort in engaging the class with ethical material.

**3.3 Pilot study**

Using data collected from the preliminary study and literature, the group determined that the best way to incorporate ethics into the BME curriculum at WPI was to use an across-the-curriculum, joint-venture approach with case studies (Graber, 2006). Case studies require the students to read about a situation, think about the different aspects and options, and involve students in the issue (Pimple, 2007). Engineering professors are generally unsure of how to teach ethics, and may not feel comfortable with leading a discussion in ethics. Having an expert in ethics lead a discussion allows for the ethical exposure of students, and for the engineering professor to gain a sense of how to incorporate ethics into the class (Zandvoort, 2008). Students may also feel more at ease with an ethics professor teaching ethics, since there is a perceived expertise. By having an expert present ethics material, the students are more likely to listen. (Trafimow, 1994).

A developed module (see Appendix B) was implemented in three BME classes: a freshman-level introductory course taught by Professor Reidinger, a sophomore-level bioinstrumentation course taught by Professor Albrecht, and a senior-level innovative design course taught by Professor Gaudette. The method of teaching ethics in all three classes was similar, using case studies and a 50 minute guest lecture from a professor in the ethics department as a guest lecturer. The case studies differed to accommodate the varying class difficulties and specializations. For example, the freshman course had a more straightforward case study on a broad topic, while the senior course had a longer, more in-depth, and specialized case study. The content of the guest lecture was left mostly to the lecturer's discretion.

A point-counterpoint assignment based on the case study was given to the students prior to the guest lecture to help students comprehensively understand the issue (Brunner, 2011). The point-counterpoint assignment was structured to be approximately two paragraphs in length, with the first paragraph defending the student's views and the second defending the views opposing their own. The engineering professor would assign the point-counterpoint as part of a homework grade to engage students in thinking alternatively.

After the completion of the first case study assignment, an ethics professor lectured the class on general ethical theories and the importance of ethics, as well as material required for thoroughly comprehending the case study assigned prior to the lecture. A post-lecture assignment was given to the students to engage in a six step analytical evaluation regarding the same case study. The post-lecture assignment asked the students to identify various ethical aspects and provide reasoning for their opinions on how to handle the situations presented in class. A student questionnaire after the final assignment served to evaluate the students' opinions on the module and whether they found it beneficial. The survey was provided to us by a psychology professor as an example of an ethics questionnaire (May, 2013; Parker, 1998; Gist, 1999). The students were given a variety of statements regarding their moral confidence and rated their confidence level from 1 to 5, with 1 being not confident at all and 5 being very confident. For example, one statement in the survey was "I can analyze a long term problem to find an ethical solution". Another statement was "I know how to deal with unforeseen ethical dilemmas". The survey consisted of a total of thirteen such statements, and students rated the same statements in the before and after surveys. Because the statements were similar and all rated moral efficacy, all of the answers were averaged to obtain one aggregate answer for each student's pre-survey and one aggregate answer for each student's post-survey. The class before and after averages were also calculated to provide a comparison to each individual. A list of the statements is provided in the Appendix C.

Interviews were conducted with all the participating professors in the expanded studies to gather input from using the module. The BME professors were asked to voice their views on the effectiveness of the module, the ease of using it, likeliness of future use, among other opinions. Ethics guest lecturers were asked to provide thoughts on module improvement, effectiveness, and general comments about the time and effort required to prepare for the ethics lecture, and whether they would participate in the future.

### 3.4 Data analysis and conferences

The survey data collected regarding moral efficacy to determine student confidence in ethical decisions were averaged together for an aggregate score and then analyzed statistically. Paired t-tests were used to determine the significance of the results with $p<0.05$ considered significant. Only data from students who had participated in both the before-module survey and after-module survey were used, as the baseline responses were needed for comparison.

After analyzing the data and collecting results, the IQP team had the opportunity to apply to the 8th International Conference on Ethics in Biology, Engineering & Medicine (ICEBEM) by submitting an abstract regarding the experiment. The team was accepted for an oral presentation at the conference, and a full manuscript has been submitted for publishing at a later date.

## IV. Results

### 4.1 Preliminary study

A preliminary study was incorporated into a sophomore level biomechanics class which exposed students to three different methods of teaching ethics: a lecture from the engineering professor, a point-counterpoint assignment, and a guest lecture. From Figure 1, it can be seen that a majority of the students, 57%, preferred the ethic professor's lecture and discussion.

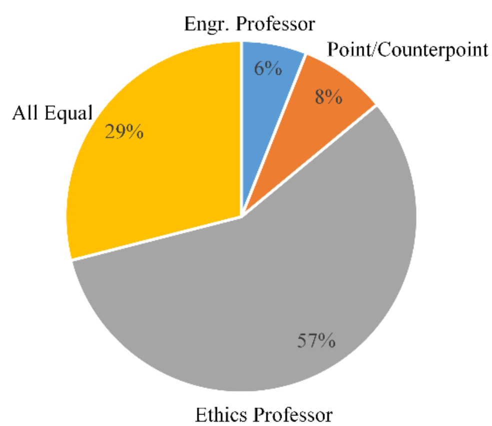


Fig. 1: Student preference of the three ways of teaching ethics from the pilot study. The majority of the students indicated a preference for the joint-venture method in a post-course evaluation, with n=60 of 85 students in a sophomore-level biomechanics class.

When interviewed, the engineering professor, Professor Billiar, also indicated that he favored the guest lecture, as he felt that the ethics professor was able to discuss the ethical theories and implications in greater detail due to his formal training in ethics. It was found that 80% of the students claimed to have learned something new from the guest lecture, and would like to see a similar ethics approach in the future. Of the students in the initial study, 75% would also consider taking a full BME ethics course in place of an across-the-curriculum study.

### 4.2 Pilot study

From the results of the preliminary study, a method based on case studies was developed centered around an expert guest lecture. This module format was implemented in each of three courses ranging from freshman- to senior-level. The courses had small to large student populations, and the modules constituted various proportions of the course grade, as seen in Table 1. The module constituted the highest percentage of course credit in the senior-level class compared to the sophomore and freshman courses. The senior class had the highest participation rate, possibly corresponding to the higher incentive. The freshman-level class also had a very high participation, with the module counting as bonus points to homework assignments. The sophomore-level class had the least amount of participation compared to the other classes, as they possibly did not have enough time due to the amount of engineering material presented by the engineering professor, but still had 75.5% participation rate.

Table 1: Expanded study with course level, number of students, and participating students

| **Course title** | **Course level** | **Number of students** | **% of course** | **Participating students** |
|---|---|---|---|---|
| Introduction to Biomedical Engineering | Freshman | 81 | Bonus points | 90.1% |
| Biomedical Signals, Instruments, and Measurements | Sophomore | 94 | 3% | 75.5% |
| Innovation in Biomedical Engineering Design | Senior | 28 | 5% | 93% |

Overall, the participating students in all three classes found the guest lectures insightful in understanding the case study assignment. Upon completion of the module, most students were more confident in facing ethical situations and would know how to handle them, as opposed to the beginning of the class. Feedback showed that the majority of participating students would like to continue seeing similar modules implemented into the BME curriculum. Table 2 shows the complete list of module opinion questions that were asked to the students, as well as the overall student responses.

Table 2: Average student responses of all three courses to effectiveness of expanded study

| Question # | Question | Yes |
|---|---|---|
| **1** | Did you find the ethics guest lecture helpful in understanding the assigned case study? | 90.5% |
| **2** | Did you learn anything new regarding how to analyze ethical situations? | 82.4% |
| **3** | If encountered with an ethical situation in the work force, would you know how to identify, analyze, and handle it? | 90.6% |
| **4** | Are you any more confident in facing an ethical situation now than you were in the beginning of the term? | 81.7% |
| **5** | Did the ethics module distract from the technical core course work too much? | 10.6% |
| **6** | Would you consider taking a full (1/3 credit) BME ethics course? | 70.6% |
| **7** | Would you want BME courses to incorporate a similar ethics module in the future? | 84.6% |

An interesting pattern in the student opinions, shown in Figure 2, is that the students felt that they learned more from the ethics module in upper-division courses than in lower-division courses

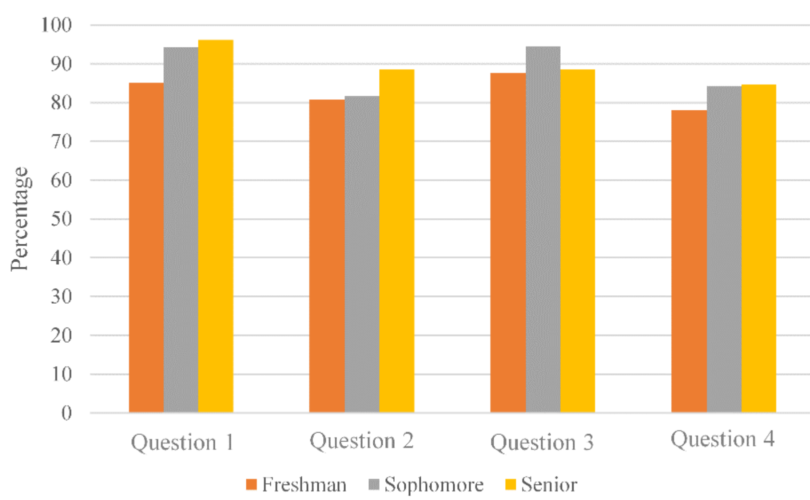


Figure 2: Visual comparison of class levels with positive student response. The questions shown correspond to the questions asked in a student survey regarding the effectiveness of the module, as shown in Table 2. The overall average positive response percentages for each question are displayed.

Only the first four questions were used from Table 2 in this comparison because these questions gathered student input on their perceived benefits of participating in the module while the remaining questions focused on the students' views of ethics in the classroom. A copy of the student opinion questionnaire is provided in the Appendix C. All three pilot courses had positive results, indicating that the majority of students felt more comfortable with ethics after participating in the module, and had learned a significant amount. However, of these results, the freshman class were impacted the least, while the senior class gained the most. For example, 80.8% of the participating freshman class felt they learned something new in the ethics module, 81.7% of the participating sophomore class felt likewise, and 88.5% of the participating senior class felt they learned something new from their ethics module.

As part of the study, the students were given a survey evaluating their moral efficacy before and after partaking in the module. Figure 3 shows the freshman class data, with a beginning class average rating of 3.77 on the confidence scale in moral efficacy. After the module, the overall confidence in the freshman class increased by 0.19 points to a rating of 3.96.

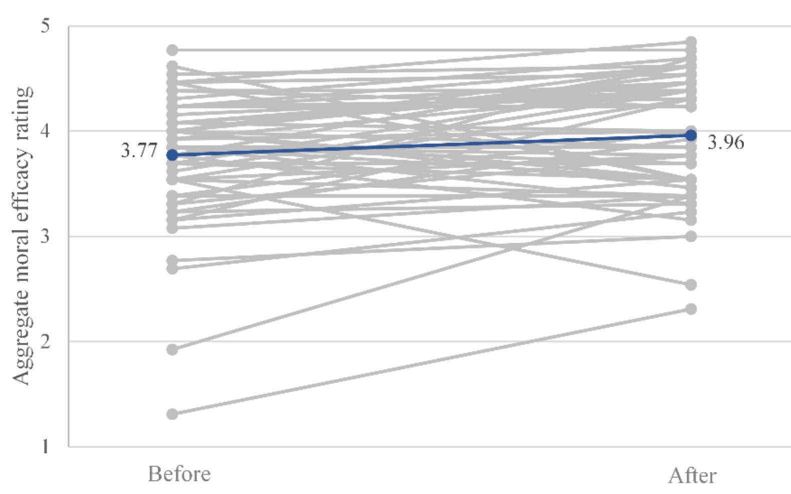


Fig. 3: Freshman class before and after survey averages of moral efficacy of each student (in gray) compared to the class average ratings (in blue). There is a general confidence increase in moral efficacy, from an average rating of 3.77 to a 3.96 class average, with n=58. Standard deviation is 0.62 before and 0.58 after. Students with lowest beginning confidence seem to have the highest gains.

The sophomore class data is shown in Fig. 4, with the lowest beginning class rating of 3.56 on the confidence scale in moral efficacy. After the module, the overall confidence in the sophomore class increased by 0.34 points to a rating of 3.90. The average sophomore class confidence levels increased the most of the three pilot courses.

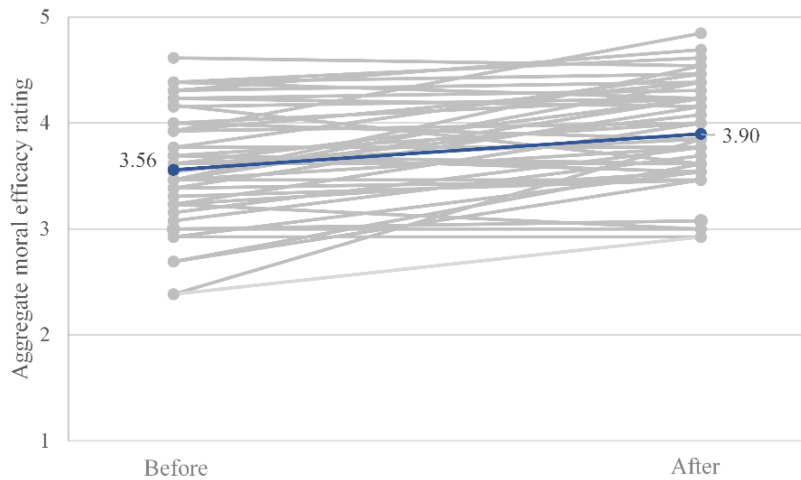


Fig. 4: Sophomore class before and after survey averages of moral efficacy of each student (in gray) compared to the class average ratings (in blue). There is a general confidence increase in moral efficacy, from an average rating of 3.56 to a 3.90 class average, with n=47. Standard deviation is 0.56 before and 0.49 after. Students with lowest beginning confidence seem to have the highest gains.

The senior class data is shown in Fig. 5, with the highest beginning class rating of 3.86 on the confidence scale in moral efficacy. After the module, the overall confidence in the sophomore class increased by 0.05 points to a rating of 3.91. The senior class had the smallest increase in confidence. The small increase does not mean the module was not effective. With only one lecture out of over twenty-five in the course, a large change in a student's ethical reasoning skills was not expected.

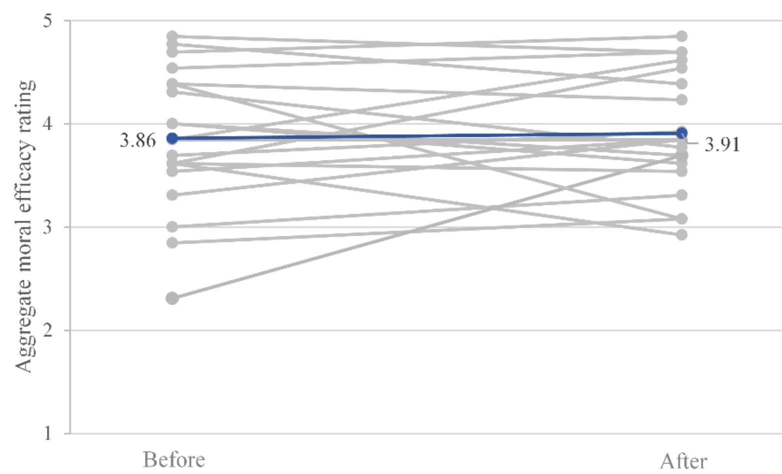


Fig. 5: Senior class before and after survey averages of moral efficacy of each student (in gray) compared to the class average ratings (in blue). There is a small confidence increase in moral efficacy, from an average rating of 3.86 to a 3.91 class average, with n=20. Standard deviation is 0.67 before and 0.58 after. The sample size of the senior class was smaller than the other classes, and seems to have the largest variance among students.

Overall, each class that partook in the module had an end confidence level of around 3.9 (out of 5) in moral efficacy. The sophomore class began with the lowest level of confidence, and the senior class began with the highest level of confidence. Statistical analysis revealed that the change in student-reported "moral efficacy" was significant at the $p<0.05$ level for the freshman and sophomore courses, but the power of the statistical test was low for the freshman course and senior course indicating a greater number of samples are needed in future studies (freshman class: $t(58)=-5.49$, $p<<0.001$, power= 0.42; sophomore class: $t(47) = -11.1$, $p<<0.001$, power= 0.93; senior class: $t(14) = -0.29$, $p = 0.77$, power = 0.03).

After the ethics module was completed, the team interviewed the BME professors and ethics guest lecturers who participated in the study to gather input on their opinion of using the module. The interview questions can be found in Appendix D. The BME professors all thought that the module was easy to incorporate into their class schedule, and the content was not distracting from the main engineering material. Given the chance, they would indeed implement the module again into future BME courses. However, one BME professor thought that the guest lecture was a bit too in-depth discussing the ethical theories, and did not explain how the ethical theories applied to the different aspects of the case study thoroughly enough, making the analysis assignment a bit challenging for the students.

In addition to compiling statistical data regarding the student responses, the final survey also included a section for general comments and opinions. The survey questions can be viewed in Appendix C. Overall, the student responses to this survey were generally positive, with 83% out of 60 responses in the freshman class, 77% out of 70 responses in the sophomore class, and 82% of 23 responses in the senior class indicating that they would like to see BME classes incorporating ethics modules in the future. The negative responses indicated that they would rather see a separate ethics course rather than shoehorning “irrelevant material” into traditionally technical courses. However, there are already several ethics courses offered, with one specifically dedicated to bioethics.

## V. <u>Discussion and Analysis</u>

Overall, the joint-venture approach showed to be both successful and popular in exposing students to ethics material. Over 80% of students in all classes indicated that they felt they could better identify, analyze, and handle ethical situations experienced in the workforce, and approximately 85% stated that they would like to see more ethical modules implemented in future BME courses. Student opinion indicated that the developed module successfully exposed them to situations with ethical components and helped to improve their ability to handle these situations. The module was not too distracting from normal coursework, as demonstrated by 89% of participating students, and interest in a full ethics course was also observed with 70% of the students indicating that they would consider taking one. In addition, interviews conducted with both the engineering and ethics professors demonstrated that the amount of time required for both parties in coordinating guest lectures and presenting material was easy to manage. Small increases in confidence in moral efficacy were also found, but the changes were not statistically significant in any of the courses.

In a broad sense, there are three primary strategies of incorporating ethics into a curriculum: the across-the-curriculum model, stand-alone courses, and the joint-venture approach (Li, 2012). The joint-venture approach takes into account that engineering faculty may not have enough background to teach ethics well, and philosophy professors may not have enough engineering experience to relate ethics with engineering. Guest lectures also break the monotony of class, keeping students engaged and interested (Lynch, 1997). The diverse specializations of various faculty members allows for many fields of expertise to be covered, incorporating both engineering material and ethics material.

It has been suggested that an integral part of learning ethics lies within understanding the various components and paths of an issue (Bebeau, 1995). In our implementation, the students were assigned a more in-depth assignment to identify the ethical points of conflict, interested parties, the possible courses of actions and their respective consequences, as well as the moral obligations of the engineer in question to ensure that the students examined different components in the case study.

Student and faculty feedback from the pilot studies was positive overall. The ethics modules were incorporated into each of the classes as homework points or bonus points, counting for varying percentages of the course. This ensured that the majority of students would participate in the ethics module. From collected responses, most students who participated in the ethics module felt more confident in facing an ethical situation, and that they would know how to handle any ethical issues that may arise in the future. An interesting note is that 70.6% of the students in the three pilot courses would consider taking a full bioethics course completely dedicated to the ethics of life sciences and engineering. Some students voiced that they wished to see the establishment of such a course in the future, indicating that most students did not even realize that a bioethics course was already available.

However, there are limitations to our findings. The senior level class was small, with fourteen students participating in the study. Therefore, their confidence in moral efficacy after the study cannot be proven to be a result of the module or coincidence. We believe this to be the result of a small sample size. In addition, the freshman class data had a low p-value, but the difference in the mean was not high enough to give a significant power. The sophomore class passed the t-test and power test, by having a p-value lower than 0.05 and a power value over 0.8, and had a mean difference of 0.34, nearly double the mean difference of 0.18 from the freshman class. Since two of the main factors of significance are sample size and mean difference, these results are not surprising. It would be beneficial to keep these results, as they provide a good foundation for future studies.

The ethics professors who guest-lectured in the BME courses all agreed that they had enough time and resources to prepare an ethics lecture for the respective classes, even though they were not specifically compensated for teaching the modules over their normal teaching load. The ethics module, in their opinion, is a good start to exposing students to more ethics and broadening their mindset. However, the ethics professors also reported that in order to fully educate the students on ethical values, there needs to be a more in depth component to their education.

A full length conference paper regarding the implementation of our modules in the BME curriculum has been submitted and accepted for publication in *Ethics in Biology, Engineering & Medicine - An International Journal*.

## VI. Future Recommendations

While our ethics modules assess and attempt to meet students' needs for proper ethics teaching within their BME courses, there is still plenty of work to be done towards implementing a formal, more complete system to address this need. The modules currently introduce the topic of ethics in individual BME classes, and give the students a few tools to help identify and navigate ethical situations. However, the modules for the scope of this project were tailored specifically for each course, and do not adequately address the larger issue of incorporating ethics comprehensively into the entire BME curriculum. Work needs to be done on how to relate the ethics modules within all the BME classes without becoming overly repetitious and monotonous for the students. Different class levels (sophomore, junior, senior) should have different levels of depth in ethics material, and ethics lessons should not be repeated. By the time a student graduates, he or she should have a complete ethics education to supplement their engineering curriculum. Because every student has a different schedule and may take different courses, there needs to be a way to ensure that every student gets the same basic background in ethics, and they are not simply learning the same lesson over and over again.

For the purpose of this project, the IQP team acted as an intermediary between the BME department and ethics professors. A new system needs to be established where a more direct means of communication is available for the joint-venture lectures. This will prevent communication errors and delays in messages. Also, the professors will be able to become better acquainted and can make the ethics lessons more relevant. We also gave the professors the authority to teach the guest lecture in whatever form they deemed fit. Some professors focused on lecturing to the students, some teachers wanted more class involvement during the discussion. There should be a way to make the guest lectures more controlled instead of letting the professors do it in whatever form they want. This would ensure that guest lectures are more consistent.

This project was generally received positively by the students and professors, but a more long term study may be necessary to observe what they think of the overall exposure in each class. All our testing was done at WPI which organizes its academic schedule and course-load in a different way than most institutions do. As such, the module would likely need to be modified and tailored to work with other schools' curricula. Further testing to see how the module is received at other schools is necessary.

## VII. Conclusion

There is a lack of ethics incorporated into engineering courses, which may leave students unaware of the importance of day-to-day decisions made in the field. This is increasingly imperative within the biomedical engineering community since they have such a large impact on the patients who use their devices and products. A method was developed to increase ethical exposure and teach students how to identify and navigate ethical situations in the context of their technical coursework The method involves giving the students a case study to examine on their own, along with a survey to gauge their initial ethical baseline. Our study incorporated ethics modules into three classes, with overall positive results. Students indicated that they were more open to ethics-based lessons, and professors in both the BME and Philosophy departments agreed that the module was effective in exposing students to potential ethical situations they may experience in a professional setting. Perhaps with further studies and adaptation of our ethics modules, an efficient and simple-to-use ethics program can be incorporated into pre-existing engineering curricula without considerable effort. Such an implementation of incorporating ethics into a class may be more appealing to engineering professors, and as a result may promote the ethical education of engineering students.

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## Appendix A: Preliminary Study Materials

### Point-counterpoint case study and assignment

Article: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3467723/pdf/586_2005_Article_BF01834062.pdf

The subjects weren't critically harmed during the experiment, and they did volunteer, but in the results section you can see that they did suffer minor injuries and general soreness. Using these people in the experiment allowed scientists to gain more insight on how automobile injuries affect the neck, and how to improve safety systems in the future. However, these 5 people were put at risk to achieve any results,
albeit "minor" risk.

Questions:
Is the justification of human experimentation in this case valid? Write a short paragraph on why or why not. Support your answer.

If you previously answered that human experimentation was NOT justified, then write a paragraph on why it IS justified. Support your new response.

If you previously answered that human experimentation was indeed justified, then write a paragraph on why it is NOT justified. Support your new response.

### Guest lecture case study and questions

You are scheduled to try your newly prototyped device in the local animal laboratory. The animal will be shared with another team who will use the animal first for their purpose before you then take over for your project. The animal lab personnel supervise the anesthesia of the animal and the surgical preparation of the animal for both teams. The protocols have been approved by the appropriate bodies for these acute experiments. You note that the animal seems to be rather 'light' on anesthesia at the end of the first protocol and you mention that to the laboratory personnel in charge. They tell you that is the right level and that you can proceed to start your work. As you make a skin incision the animal moves and makes a noise around the endotracheal tube. You tell the laboratory person in charge that you are uncomfortable with the animal's reaction but he says that reaction is usual and you are just unfamiliar with this kind of work.

Pre-lecture question:

Will you continue with the procedure and 'get used to' the animal's reactions, or will you stop the procedure and lose the opportunity to use your device? Why?

Post-lecture questions:

Did the guest lecture from Professor Pfeifer improve your understanding of the case study? If so, how?
Would your actions in the situation presented in the case study change after the lecture?

**End of module student feedback survey**

1. This term, portions of three lectures were dedicated to promoting ethical exposure. Of the three ethics-based lectures, which did you most prefer?
a. Professor Billiar led lecture
b. Point/Counterpoint Assignment
c. Guest Lecture with Professor Pfeifer
d. None of the above

2. Which of the three lectures did you feel you gained the most from?
a. Professor Billiar led lecture
b. Point/Counterpoint Assignment
c. Guest Lecture with Professor Pfeifer
d. None of the above

3. Were the ethics lectures useful at all? Did you learn anything new?
a. Yes
b. No

4. Would you want BME courses to incorporate similar ethics modules in the future?
a. Yes
b. No

5. Were the ethics modules too distracting from the core course work?
a. Yes
b. No

6. Would you consider taking a full BME ethics course (1/3 credit dedicated entirely to engineering ethics)?
a. Yes
b. No

**Appendix B: Core module**

1. Baseline survey for students to determine where initial student standing on ethics in engineering (see Appendix C)

2. Assign the case study reading for homework, and have the students answer a couple questions regarding the study (may count as part of a homework grade, bonus points, or any % of final grade at the professor's discretion). The paragraph will consist of the student's position regarding the issue and their defense/reasoning, and then the opposite position and defense. The IQP team will provide the assignments as necessary.

3. A 50 minute guest lecture by an engineering ethics professor who will lead the students through a discussion regarding the case study assignment. However, the lecture will be left largely up to the guest lecturer's discretion, who will adhere to their professional opinion on what would be the best use of time allotted. The BME professor will choose the dates of the lectures.

4. Assign another assignment regarding the case study, this time asking the students to identify the ethical issues in a study, the stakeholders, the different courses of actions and their respective consequences, and the moral responsibilities of the person in the article. Research shows that this helps the student better understand the issue at hand and better support their own position. The assignment will be drafted by the IQP, and given to the professor for approval.

5. A follow-up survey will be given at the end of the course. This will be used to determine any change in the student's ethical knowledge, and the students' opinions of the ethical module

## Appendix C: Pilot courses materials

### Freshman-level case study

From NIH website on Intellectual Property and Genomics. Retrieved from: http://www.genome.gov/19016590

Whether or not genes can be patented has been debated since the inception of the Human Genome Project. At the heart of the debate have been questions about whether discovery of a gene is sufficient to claim an invention and whether gene patents encourage or stifle research and the clinical use of genomics. In a landmark decision in June 2013, the Supreme Court determined that DNA in its natural form cannot be patented.

The earliest genetic patents were issued in 1982, following the U.S. Supreme Court case of Diamond vs. Chakrabarty, which opened the door to patenting biotechnology discoveries. Since then, the core of the debate over gene patents has been whether or not the discovery of a gene or sequence of DNA rises to the level of invention required by Title 35 of the United States Code, which lays out the criteria that must be satisfied for a patent to be granted. According to the Code, a patent may only be granted on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Laws of nature, natural phenomena, and abstract ideas cannot be patented. Even if this first hurdle is passed, the invention must be novel; the existence of 'prior art' shows that someone else invented it first, of course. Also, the invention cannot be obvious to "a person having ordinary skill in the art to which said subject matter pertains."

In the case of gene patents, critics have pointed out that such patents fail to meet most or all of these criteria. Firstly, genes are naturally occurring, and while much intellectual effort may have gone into discovering them within the DNA sequence, discovery is not the same as invention. Secondly, with the completion of the Human Genome Project in 2003 all of the human gene sequences were in the public domain and, therefore, prior art. And, finally, many argued that discovering the location of a gene never rose above the bar for being non-obvious; certainly by the late 1990s the practice was common place. DNA patenting has proven to be a very active area, despite the controversy of patenting genetic information that was discovered and not created. Although it is difficult to determine a precise number, some estimates assert that a fifth of the human genome is subject to patent claims.

Patents are issued to encourage innovation, and provide protection to allow those investing in an innovation the opportunity to maximize the profit from their investment. Patents issued for genetic technologies such as new methods of DNA sequencing are no different and their issuance has been extremely valuable to those developing products based on genetic discoveries. However, when patents limit the use of basic genetic information, they threaten to inhibit or unduly constrain biomedical research, and the translation of research discoveries to clinical applications.

Indeed, one of the early principles agreed upon by leaders of the Human Genome Project was that the DNA sequence generated should be freely available to the public. This principle was codified in the 1997 Bermuda Principles, which set forth the expectation that all DNA sequence information should be released into publicly available databases within 24 hours of being generated. This policy of open access to the genome has been a core ethos of genomics ever since.

Over the years that this debate has occurred, there have been concerns that large numbers of patents associated with the human genome would limit the integration of genomic medicine into health care because of either restrictive patents or prohibitive costs. Diagnostic tests on patented genes cannot be invented around, as is possible with other patents. This is because the actual DNA sequence to be tested is claimed in the patent, not the method of analyzing the gene to determine its sequence, and so only the patent holder, or their licensees, have the rights to sequence that DNA during the patent's life.

In addition, so-called "patent thickets," where multiple patent holders stake their claims across the genome, could have the potential to inhibit the translation of genetic discoveries into health care benefits. Patent thickets have occurred in other technological domains when multiple patent holders have related claims; for example in consumer electronics or standards for digital video and music.

In April 2010 the Secretary's Advisory Committee on Genetics, Health and Society published a report, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. Resting on the underlying assumption that patents on human genes were acceptable, the report recommended that diagnostic (but not therapeutic) genetic tests, be exempted from patent infringement, along with a research use exemption. Exempting diagnostic patents from infringement while still recognizing that diagnostic gene patents could exist was greeted with controversy at the time, especially considering that the case studies that accompanied the report showed mixed evidence of harm to patients as a result of gene patents.

The debate about gene patents was already a hot topic at the time of the early Congressional deliberations about the U.S. involvement in the Human Genome Project. Congressional worries about the potential effects of gene patents resulted in a statutory mandate to the National Human Genome Research Institute to research 'legal issues regarding patents' as part of the then Center's research into the ethical, social, and legal implications of human genome research.

Indeed, such were the concerns over the patenting of human genes that, in 2001, then-NIH Director Harold Varmus, and then-NHGRI Director Francis Collins wrote to the U.S. Trademark and Patent Office (USPTO) urging them to implement stricter criteria for biotechnology patents. USPTO raised their bar for issuing such patents, with new guidelines stating that identification of a gene's sequence alone is not patentable, but that a gene isolated from its natural state may be patentable if the applicants can demonstrate "specific, substantial and credible utility" for the discovery. See: United States Patent and Trademark Office Utility Examination Guidelines (2001).

How patent holders license the gene patents they have been issued has also been a critical component of the ethical discussions about genetic intellectual property. A patent that is widely or, in some cases, even freely licensed does not pose the same types of impediments to the implementation of genomic medicine as a patent that is exclusively licensed. To explore the range of issues implicated in consideration of genetic intellectual property practices, NHGRI, in partnership with other NIH institutes, commissioned the 2005 National Academies report

Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health.

NHGRI worked extensively with the NIH Office of Technology Transfer to develop Best Practice Guidelines for the Licensing of Genomic Inventions, published in 2005. The institute, in partnership with other organizations, has worked actively on these issues in an effort to maintain a level of access to basic genomic data able to achieve maximum public benefit through freedom to operate for researchers and care providers.

In 2009, the questions regarding gene patents finally went to court when the Association of Molecular Pathologists, the American Civil Liberties Union, and a coalition of other groups, filed a lawsuit against Myriad Genetics, the USPTO, and the University of Utah Research Foundation. The suit challenged the constitutionality and validity of the BRCA1 and BRCA2 gene patents. Myriad Genetics had been particularly active in enforcing their exclusive license to these breast cancer genes, sending cease and desist letters to other labs and even researchers it felt were infringing its intellectual property. Critics of the company also pointed to the test's high price and the fact that it created a health disparity between those who could afford to be tested and those who could not.

The case was first heard in the United States District Court for the Southern District of New York and in March 2010, District Judge Robert Sweet ruled in favor of the plaintiffs [graphics8.nytimes.com] and against Myriad Genetics, finding that the BRCA1 and BRCA2 genes were products of nature and therefore not patentable material. Judge Sweet's ruling made the important point that it is the information encoded in a gene, and not just the molecular structure, that makes them valuable to the patent holder. Since the raw information encoded in a gene is a product of nature, Judge Sweet asserted that it was not patentable under section 101 of Title 35 of the U.S. Code.

Myriad and the other defendants appealed Judge Sweet's decision, and so the lawsuit over gene patents moved on to the Court of Appeals for the Federal Circuit. This court affirmed part of Judge Sweet's ruling but the ruling on Myriad's claims to the isolated genes were reversed in a 2-1 ruling (in favor of allowing Myriad to hold the patents). Writing the opinion, Judge Alan Lourie rejected Judge Sweet's argument about the information content of a gene, and focused on the fact that isolating a gene broke the covalent bonds between the molecules within the DNA, thereby creating a new substance. Judge Kimberly Moore concurred in part with Judge Lourie, also finding Myriad's claims to the isolated BRCA genes patent-eligible, not because they were new substances but because USPTO had been granting such patents since the 1980s, and she believed that throwing them out would be too disruptive to the biotech industry.

The plaintiffs appealed this decision to the U.S. Supreme Court, but following their 2012 ruling in another diagnostic patent case, the Supreme Court returned it to the Federal Circuit for reexamination. Upon reexamination, the Federal Circuit arrived at the same decision as in their first ruling, upholding Myriad's core claim on the isolated gene sequence information. The case again was appealed to the Supreme Court, who heard oral arguments on the question of whether isolated human genes are patent-eligible subject matter in April 2013.

On June 13th 2013, the Supreme Court published their ruling in the case, unanimously finding that isolated but otherwise unmodified genes were products of nature and therefore not patent eligible subject matter. However, the court did find that cDNA, synthetic DNA molecules that contain only the exons of a gene, do involve an inventive step, and thus remain patent eligible. The opinion, written by Justice Clarence Thomas, agreed with Judge Sweet's 2010 argument that the information content of a gene was as important as its chemical structure. The court's opinion also agreed with a friend of the court brief, filed by the U.S. Department of Justice on behalf of the federal government when the case was before the Federal Circuit in 2011 (and again in a modified form when the case went before the Supreme Court in 2013). In this brief, the government took the position that isolated, but otherwise unmodified DNA should not be patent eligible, but that cDNA should be patent eligible. NIH and NHGRI are very pleased with the Supreme Court's ruling in this case, and the removal of serious potential roadblocks that could impede the widespread adoption of genomic medicine.

**Sophomore-level case study**

From Bruley, M. (2013). Case studies of medical device adverse events. Accident and Forensic Investigation.

A community hospital had traditionally used reusable quartz pressure transducers of the same brand as the physiologic monitors with which they were used. Wishing to cut reprocessing costs for the reusable transducers, the hospital began to evaluate disposable pressure transducers for use in clinical areas—namely, anesthesia, recovery, intensive care, and cardiac care.

The decision to evaluate disposable transducers was initiated by one of the hospital's departmental purchasing agents who gained physician approval and coordinated the purchase process on his own. He contacted a manufacturer of disposable transducers and met with one of its sales representatives, and arrangements were made for an in-service presentation by the transducer manufacturer. All nurses from the intensive care unit (ICU), cardiac care unit (CCU), anesthesia unit, and post-anesthesia care unit attended.

The sales representative presented an on-site program for day-shift nurses; evening- and night-shift nurses watched a manufacturer-produced videotape. These programs did not include an actual setup of a transducer to a patient monitor. The facility subsequently received shipment of the disposable transducers and began an in-house trial of the device.

One use during the in-house trial was on a 70-year-old female patient with a diagnosis of metastatic cancer of the breast, who was transferred to the hospital's CCU. Her attending physician inserted a Swan-Ganz catheter into the right pulmonary artery, as well as an arterial line catheter. The Swan-Ganz catheter was connected to a newly introduced disposable transducer. The arterial line catheter was connected to one of the old-style reusable quartz transducers. Both lines were connected to the blood pressure module housed within the physiologic monitor made by the manufacturer of the reusable quartz transducer. This was the first time that the CCU had ever used a disposable blood pressure transducer.

Upon insertion, the invasive pulmonary artery blood pressure readings from the Swan-Ganz line were very low. The digital numbers on the display monitor were low, and the graphically displayed waveform appeared "damped." Pressure readings from the arterial pressure line were within normal physiologic range. Nurses re-zeroed the disposable transducer on the Swan-Ganz catheter three times, but the readings remained low. IV fluid therapy was immediately initiated. The disposable transducers being used for the first time in other areas of the hospital were also exhibiting problems at this time, but not necessarily the same ones. Anesthesia personnel attempted to use one during surgery. They could not zero the transducer and switched back to the old-style reusable transducer. After this incident, the hospital contacted the disposable transducer representative, who corrected the problem by changing the cable. No hospital staff other than those present were made aware of the problem. The physiologic monitor used in surgery is of the same brand but is a newer model than those used in the CCU and ICU.

Coincident with this patient's seemingly problematic pressure readings, the ICU contacted both the departmental purchasing agent responsible for the purchase of the disposable transducers and the hospital's on-call biomedical technician about an inability to get an accurate waveform and digital readout from an arterial line connected to a new disposable transducer. The biomedical technician was unable to correct the problem. He substituted the disposable transducer with one of the newer model physiologic monitors that were being used in the surgical suite. This was the first time that the biomedical technician learned that the hospital was using disposable transducers. No further action was taken at the time.

The evening house supervisor (on the 3:00 p.m. to 11:00 p.m. shift) was aware of the ICU problem and informed the incoming night supervisor not to use disposable transducers for arterial lines. Nothing was said about using the disposable transducers for Swan-Ganz lines used for monitoring venous or pulmonary artery pressures. The disposable transducer used on the CCU patient was not changed. At about 36 hours after the low pulmonary artery pressures had been seen and fluid therapy started, the CCU patient's Swan-Ganz catheter waveform became completely flat. A nurse who had previously heard about the ICU's problem with the disposable transducer replaced the disposable transducer with a reusable Hewlett-Packard transducer. A good waveform was immediately obtained, and the Swan-Ganz readings were within normal range. No further action was taken.

The CCU patient died approximately three hours later. Postmortem examination determined that the cause of death was from massive fluid overload.

Investigation by the risk manager and clinical engineer revealed that the older model physiologic monitors have an internal blood pressure transducer sensitivity selector switch, which is accessible to engineering staff only through the top metal plate of the pressure module. The switch on the older-style CCU monitor was set for reusable transducers, not disposable transducers, thus yielding erroneously low Swan-Ganz readings. The clinical engineer knew of this feature of the older—but still clinically acceptable—monitors. Unfortunately, he had not been consulted during the purchasing process for the disposable transducers that were to be used with the capital equipment monitors. The newer monitors had a sensing circuit that would automatically adjust the monitor's transducer sensitivity setting.

Equipment evaluation and purchasing processes were changed at the facility to ensure that any disposable device that is connected to a piece of capital equipment was tested for compatibility. Further, hands-on, in-service training for use of such disposables was mandated.

**Senior-level case study**

From Bailey, R. and Schleiter, K. (2010). Testing Manufacturer Liability in FDA-Approved Device Malfunction. AMA Journal of Ethics. 12 (10): 800-803.

In 1996, an Evergreen Balloon Catheter, marketed by Medtronic, Inc., burst during Charles Riegel's angioplasty [1]. The catheter had been granted premarket approval (PMA) from the Food and Drug Administration (FDA) in 1994. While the manufacturer's instructions recommended that physicians inflate the catheter to only 8 atmospheres, the treating physician in Riegel's case inflated the catheter to 10 atmospheres before it burst. As a result, Riegel developed a heart block, was placed on life support, and underwent emergency coronary bypass surgery. Riegel and his wife filed a product liability complaint against Medtronic. A federal district court dismissed the complaint, holding that federal legislation—the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act [2] preempted the state negligence and liability claims the Riegels cited in their case against Medtronic. The case eventually made its way to the U.S. Supreme Court. *Riegel v. Medtronic, Inc.* brings to light a conflict between manufacturers who have obtained FDA approval and injured patients who want to retain the option of seeking restitution for damages resulting from defective medical devices [3]. Patients who believe defective devices caused their injuries take little comfort in knowing that the devices had FDA approval. Conversely, device manufacturers who received FDA approval after extensive review want to avoid repeating the review process in the courts. In *Riegel*, the Supreme Court addressed whether the preemption clause of the Medical Device Amendments bars state law claims that challenge the safety and effectiveness of a medical device given premarket approval by the FDA.

The Medical Device Amendments (MDA) of 1976 established three regulatory classes of medical devices. Class I medical devices, which include elastic bandages and examination gloves, are subject to "general controls," such as labeling requirements [4]. Class II medical devices, which include powered wheelchairs and surgical drapes, are subject to "special controls," such as performance standards [4]. The most regulated medical devices are those in Class III, which the amendments define as devices that support or sustain human life, are "of substantial importance in preventing impairment of human health" or "present a potential, unreasonable risk of illness or injury" [4]. Class III medical devices include replacement heart valves and the catheter used on Charles Riegel. These devices are subject to a rigorous premarket approval (PMA) process that includes:

- full reports of all studies and investigations of the device's safety;
- a complete statement of the device's components, ingredients, and properties;
- a detailed description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device;
- samples of device components required by the FDA; and
- a specimen of the proposed labeling [1].

The FDA grants premarket approval to Class III devices only after determining that there is reasonable assurance of their safety and effectiveness [5]. In making this determination, the FDA weighs any probable benefit to health from the use of the device against any probable risk of injury in light of available alternatives. For example, a ventricular assist device for children with heart failure was approved, despite a survival rate of less than 50 percent in children using the device, because no other device had a higher survival rate [1]. However, a Class III device that fails to meet PMA requirements is considered unmarketable [4]. At issue in *Riegel* was the Medical Device Amendments' preemption clause. In general, preemption clauses provide that federal laws that conflict with state laws will trump, or "preempt" them [6]. The preemption clause in the Medical Device Amendments prohibits states from establishing a requirement with regard to any device intended for human use that is different from, or in addition to, any federal requirement applicable to the device [5]. The preemption clause also forbids states from establishing any requirement that relates to the safety or effectiveness of a device intended for human use [5].

The dispute in *Riegel* centered on the amount of regulation necessary to ensure the safety and effectiveness of medical devices. Medtronic argued that letting state claims proceed against devices that had passed the premarket approval process would usurp the power of the FDA, because the PMA process was designed to assure the safety and effectiveness of medical devices [7]. The Riegels countered that Congress never intended the FDA's power to regulate medical devices to negate the right of private citizens to sue negligent manufacturers [8]. The Riegels also contended that FDA regulations alone were not enough to protect consumers, since no amount of rigor in the premarket approval process could predict all possible outcomes or problems with a device and its use. Without the threat of litigation, the Riegels argued, manufacturers could attempt to hide safety flaws from the FDA [9]. Medtronic challenged the plaintiffs' assertion that the threat of litigation would improve product safety. Instead, it argued, state restrictions would reduce innovation in the development and availability of beneficial medical devices [7]. Moreover, Medtronic argued, because manufacturers factor the cost of potential litigation into product prices, increasing the threat of litigation would increase the cost of health insurance and put some devices out of reach of potential consumers [10].

To settle this dispute, the Supreme Court turned to judicial precedent and the plain text of the Medical Device Amendments' preemption clause. In particular, the Court relied on its 1996 decision in *Medtronic v. Lohr*. In *Lohr*, the Supreme Court had ruled that the Medical Device Amendments preempt state requirements only when the FDA has established "specific counterpart regulations or there are specific requirements applicable to a particular device" [11]—in other words, only when the FDA has a regulation that covers the same safety aspect or the same device that the state requirement covers. The Court rejected the Medtronic contention that general labeling requirements for all medical devices fall under this "specific counterpart" description [10]. Unlike general labeling requirements, premarket approval entails an in-depth review of a specific medical device. Writing for the majority, Justice Scalia stressed that the premarket approval process for medical devices is one that is rigorous and highly individualized [1]. The Court held that because "premarket approval is specific to individual devices" it constitutes "federal safety review" which, under the Medical Device Amendments, preempts state law [1]. Because the Medtronic catheter that burst during Charles Riegel's angioplasty had premarket approval from the FDA, state claims against its manufacturer were invalid under the Medical Device Amendment and *Lohr* [1]. In support of this holding, Justice Kennedy emphasized during oral arguments that, if state law damage claims were not preempted by federal regulations, state juries would be asked to repeat the demanding review process already completed by the FDA for any potentially hazardous device [3].

By ruling against the Riegels, the Supreme Court refused to allow injured patients to sue device manufacturers whose products pass the FDA's findings of adequate safety. This ruling prevents courts from enforcing state regulations on medical devices with premarket approval unless those restrictions are identical to corresponding FDA restrictions. Going forward, this may prevent consumers injured by such devices from receiving adequate compensation [8]. Though consumers are not completely without legal recourse—they can still bring suit against negligent manufacturers under state laws identical to FDA requirements or against negligent physicians—the Supreme Court has immunized PMA medical devices from many product liability suits founded in state law, leaving some injured consumers without a common source of judicial remedy [1, 10].

Citations for senior-level case study:

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9. Brief of AARP et al. as amicus curiae in support of petitioner. Riegel v Medtronic. 552 US 312 (2008) (No. 06-179).
10. Young HF, Weiner RN, Brackey SM. Brief of Product Liability Advisory Council, Inc. as amicus curiae in support of respondent. http://www.abanet.org/publiced/preview/briefs/pdfs/07-08/06-179_RespondentAmCuPLAC.pdf. Accessed August 2, 2010.
11. Medtronic, Inc. v Lohr et vir. 518 US 470 (1996). http://supreme.justia.com/us/518/470/. Accessed September 10, 2010.

**Heuristics assignment**

This assignment is designed to guide the student through a basic ethical analysis of a situation or case study.

Regarding the ethics case study discussed in class:

Identify the ethical issues present in the case study. Ethical issues can be the moral concerns or areas where right and wrong are unclear. For each issue, explain why it is problematic.

1. Identify the stakeholders involved for each issue.
2. Identify the moral responsibilities of the stakeholders.
3. Identify the possible courses of action regarding the ethical issues. How can the issues be solved?
4. Identify the consequences to the different courses of action. What can happen?
5. For each issue, which course of action would you choose to solve the problem, and why?

**Moral efficacy survey**

1. I can analyze a long term problem to find an ethical solution.
2. I can represent my work ethically to management.
3. I can make suggestions to management for an ethical problem.
4. I can present ethical information to a group of colleagues.
5. I can write a proposal to resolve an ethical problem.
6. I can remain calm when facing ethical difficulties.
7. I know how to deal with unforeseen ethical dilemmas.
8. If someone opposes me, I can find ethical means to get what I want.
9. I can usually handle whatever ethical situation I find myself in.
10. I am confident that I can deal with unexpected ethical events.
11. I can solve most ethical problems if I invest the necessary effort.
12. I can always manage to solve difficult ethical problems if I try hard enough.
13. It is easy for me to stick to my aims and accomplish my goals while maintaining ethical standards.

**Student opinion and feedback questionnaire**

1. Did you find the ethics guest lecture helpful in understanding the assigned case study?
2. Did you learn anything new regarding how to analyze ethical situations?
3. If encountered with an ethical situation in the workforce, would you know how to identify, analyze, and handle it?
4. Are you any more confident in facing an ethical situation now than you were in the beginning of the term?
5. Would you want BME courses to incorporate a similar ethics module in the future?
6. Did the ethics module distract from the technical core course work too much?
7. Would you consider taking a full BME ethics course?
8. Do you have any recommendations on how to improve our ethics module?
9. Do you have any additional feedback/comments/concerns?

## Appendix D: Interview questions

### Ethics professor interview

1. Did you have enough time and resources to prepare a lecture for the given case study?
2. What is your opinion of the module? Do you think it is effective in increasing ethical awareness?
3. Are there any ways in which our module can be improved? For example, making it easier for the BME and ethics professors to coordinate the content of the lecture or increase student retention of ethics.
4. Would you be willing to give a similar lecture to other BME courses in the future?
5. In your opinion, if a similar synchronized module was implemented in all BME courses across the department, would it provide proper ethical exposure/understanding to students?
6. Would you want compensation to give these guest lectures on a more consistent basis in the future?
7. If we implemented the ethics module across the BME curriculum, we would need to vary the level of ethical material based on student year (freshman, sophomore, etc) in order to increase their level of understanding incrementally. Do you have any ideas on how we should organize this or any areas of ethics we should focus on in certain student years?
8. Would it be better to have a stand-alone ethics course, an across-the-curriculum module (similar to ours), or a combination of both?

### Engineering professor interview

1. Was the module easy to incorporate into your syllabus?
2. Did you think the content was too distracting from the regular course work?
3. Was the module time efficient? Would you be willing to devote more class time for ethics?
4. Was the module easy to use and understandable?
5. Would you be willing to implement a similar module in your BME courses in the future?
6. Do you think the students learned anything from our module?
7. If a systematic, inter-departmental ethical module was implemented (interviewers may need to elaborate), would you be willing to coordinate with an ethics professor to organize ethics lectures? For example, our IQP group acted as an intermediary between the humanities and BME department to coordinate the lecture/material. In the future, the BME department and/or professors would need to communicate directly with the ethics professors.