AC 2011-2272: A STUDENT-CENTERED COURSE FOR INTEGRATION OF ETHICS INTO A BIOMEDICAL ENGINEERING RESEARCH EXPERIENCE FOR UNDERGRADUATES

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A Student-Centered Course for Integration of Ethics into a Biomedical Engineering Research Experience for Undergraduates

1.0 Introduction

A number of recent, well-publicized incidents of irresponsible conduct in biomedical research emphasize the importance of training students in research ethics. In addition, the interest of the general public on ethics in government-funded research continues to rise, and new regulations require ethics training of students and other trainees as a requirement for some government-funded grants.[1,2] Many institutions provide web-based ethics training. These online training modules typically test on knowledge of the history of biomedical ethics (The Nuremburg Code, Tuskegee, etc.) and institutional policies for research ethics (animal studies, patient consent, etc). They are not likely to involve more nuanced training in contemporary issues in research ethics in order to appropriately handle the complex issues without clear answers that can be encountered in research environments. While the importance of research ethics training is accepted, the best way to develop students who can address complicated ethical issues in a sophisticated fashion is not clear.

From 2006-2010 we have run a 10-week NSF-funded summer Biomedical Engineering Research Experience for Undergraduates (REU) at the Illinois Institute of Technology. One of the primary goals of this program is to integrate ethics training into the student experience. This is accomplished primarily through a weekly ethics course in which the students are expected to think about how the ethical topics relate to their overall research experience. The achievement of this goal has required a continual refinement of the course and its assessment. In this paper we describe the evolution of this course from instructor to student-led course and evaluate the

success of the course in improving the students' ability to identify and evaluate complex ethical decisions in biomedical research.

2.0 Methods

2.1 Program

From 2006-2010, 15-20 students participated annually in this 10-week summer REU program. Students were paired with research mentors and expected to complete a challenging research project focused on engineering approaches to the study and treatment of diabetes and its complications. In addition to research, students were involved in a weekly, one hour course on research ethics. The course involved two engineering faculty and two members of the campus ethics center (an ethics professor and a librarian with an expertise in research ethics). An ABET style syllabus was developed for the course (see the appendix). While topics varied somewhat from one year to the next, the topics were generally composed of the areas shown in Table 1. The details of the course have evolved over the lifetime of the program as described below.

Table 1: Typical Topics Covered in Ethics Course
Codes of Ethics
Advisor/student relationships
Issues facing women and underrepresented groups
Intellectual Property
Authorship
Conflicts of Interest[3]
Statistics/bias
Animal Studies
Human Studies

2006-2007

In the first two years of funding, the ethics course was delivered in a traditional instructor-lead setting. The grant PI (a biomedical engineering researcher) gave presentations on each topic, attempted to integrate anecdotes related to the topics and his own personal experience, and members of the ethics center participated in the discussion. The instructor and other instructors tried to encouraged and initiate student interaction. In 2007, students were assigned additional readings to supplement lectures in the online course OpenSeminar in Research Ethics (OSRE, openseminar.org/ethics) and developed modules for OpenSeminar specific to research ethics in biomedical engineering.

2008-2010

Starting in 2008, the course format was modified in an attempt to engage students more fully in the learning process. Classes and discussion were to be student led. Students were divided into groups of two and assigned a specific topic from Table 1. The groups were expected to provide a presentation on the topic and guide class discussion. The student groups provided the class with a two page summary of their topic. In order to prepare for the lectures each group was expected to read sections on the openseminar.org/ethics web course, discuss the topic with graduate students in their lab, get input from their research mentor, and to interact with members of the ethics center. Each group developed the following:

- a summary of the topic with a handout/outline and a powerpoint presentation
- a case report that exemplifies issues that may be encountered with questions for class discussion
- assessment methods to be used as pre and post tests for the topic

Drafts of these items were submitted to the instructors two days prior to the class meeting time for feedback. In 2010 students were also required to post their case study on an ethics blog after the class meeting time and all students were required to comment on the case through the blog.

2.2 Assessment

In years 2007 and 2008 pre and post tests were implemented with simple multiple choice and true/false questions. From 2007-2009 program exit surveys were applied whether they were asked how much they enjoyed program activities, including the ethics course. Responses were indicated on a 5-point Likert scale with 1 = poor; 3 = neutral, 5= excellent. In 2009 and 2010 a more extensive assessment program was applied. Multiple sources of formative assessment were built into the course. An ethics case study was provided to the students prior to the beginning of the semester (see appendix). The case study requested student feedback first in narrative form and then responses to questions designed to assess specific aspects of their approach to the problem. A post study case report (of a different situation in research ethics, see appendix) was administered in the same fashion upon completion of the 10-week program. In both cases students were allowed as much time as needed to complete the evaluation. After reading a scenario, they first completed their response to the question "Describe any ethical issues in this situation and how the student may go about resolving those issues?" in narrative form. Once that response was complete they answered the short answer questions. A grading rubric was developed to assess student performance on the pre and post case studies.

Short answer pre-tests were developed by the students presenting on a given topic in conjunction with the faculty members and administered prior to each lecture. The undergraduates also provided case studies and questionnaires that were completed at the end of the course. The pre-tests were administered again upon completion of the course in order to assess learning in the

specific topic areas.

3.0 Results and Discussion

In 2007 and 2008 exit surveys with students generally identified negative opinions on the instructor-led research ethics course. Students struggled to identify its relationship to research experiences in general and their projects specifically. After the first run of the student-led course in 2009 students were more enthusiastic about ethics when they led the discussions and based the discussion on concepts from their own research (Figure 1).

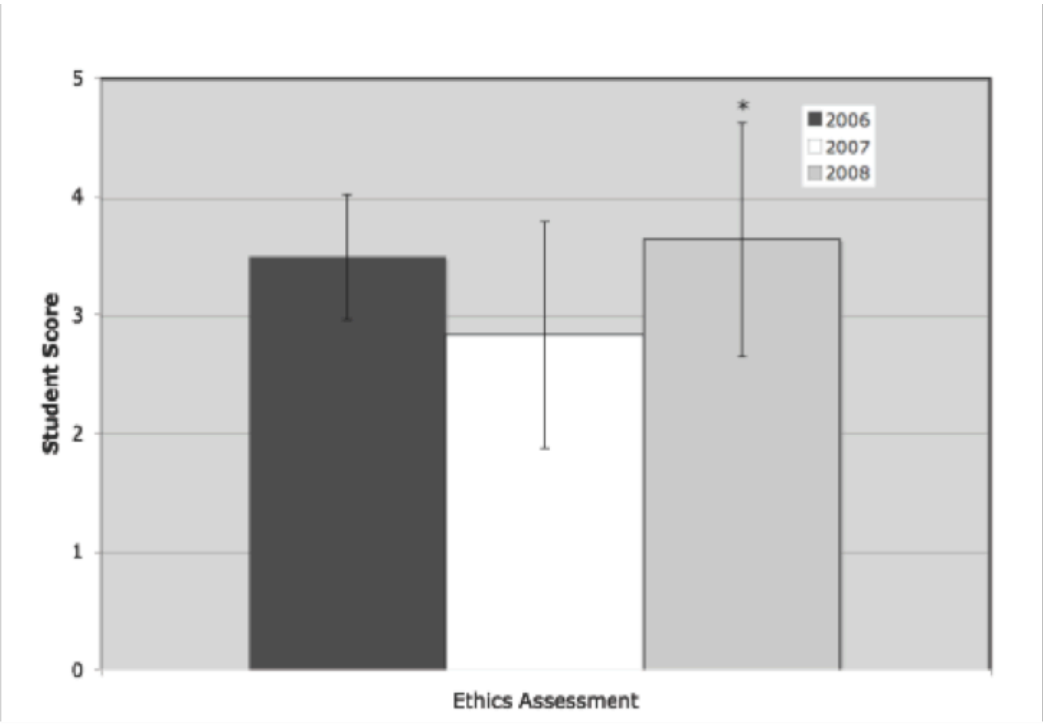

Figure 1: Summary of student surveys on ethics integration. Data are mean ± standard deviations. In year 3 (i.e., 2008) when students led discussions they gave the highest points to the ethics integration. * indicates statistical significance from 2007 ($p=0.014$, unpaired Student's t test).

The current implementation of the program and its assessment began in 2009. In this version students were to develop case studies for discussion, and a more sophisticated assessment approach was employed. In this course students were given relevant case studies involving ethical conflicts in biomedical research as pre- and posttests (see the appendix). For each case the students were asked to identify potential ethical issues, to describe who were involved, and how the conflict could be resolved. As follow-up, the students were asked a series of questions to guide their thinking and to sharpen their responses, i.e., make their responses more exact.

The responses from the students were analyzed and clustered by two of the authors. Through this process categories of answers were revealed; some relevant (applicable) to the situation and some irrelevant (not applicable). Tables II and III show the ethical categories that were identified in the different case studies. These were determined from the students' general responses to the pre- and posttest case studies. In addition, the percentage of students whose responses fell within each category has been included.

Table II. Categories extracted from student responses to pretest case study

Ethical categories	% of students responding (n = 15)
Notebook/record keeping/validation	29
Student/advisor relationship	71
Authorship and responsibility	64
University personnel	21
Publishing faulty data	50
"Need" to produce agreeable results	43

The case study for the pretest (shown in its entirety in the appendix) describes a junior-level graduate student attempting to learn a new laboratory technique and in the process reproduce results previously published by a senior-level graduate student in the lab, his advisor, an undergraduate in the lab, and a collaborator from another institution. Conflict arises when the junior-level graduate student cannot reproduce the results and believes that the senior-level graduate student may have fabricated them.

Students were asked to describe potential issues in research ethics that could arise from this situation, who could be impacted by these issues, and how the junior-level student could address/resolve these issues. The ethical issues they identified were categorized as shown in Table II.

Table III. Categories extracted from student responses to posttest case study

Ethical categories	% of students responding (n = 15)
Intellectual property	80
Policies (lab, dept., college)	30
Conflict of interest	13
University personnel	47
Student/Advisor relationship	70

The case study for the posttest (again, shown in the appendix) describes a situation in which a senior-level graduate student has defended her thesis and has landed a new job with the help of her advisor. Conflict arises, however, when the advisor requests that the student leave

most of her research materials in the lab (including her lab notebook, data, and files). In addition, the student's advisor provides her with a list of areas that he expects her not to work on in the future.

Similar to the pretest, students were asked to describe the potential ethical issues in this scenario and how the student may be able to resolve them. The ethical issues they identified were categorized as shown in Table III.

A comparison of the categories listed in Tables II and III with the topics addressed in the course (see the course syllabus in the appendix) shows the students using more specific terminology from the course on the posttest. In addition, the students on the posttest hone in on the more important issues such as intellectual property and student/advisor relationships a greater percentage of the time than they do on the pretest. As shown in Table II, students often cited the "need to fit into the lab", or "problems with publishing faculty data", not recognizing that these issues fall under the more general topics of student/advisor relationships and responsibilities of authorship.

Similar to the general responses to the pre- and posttest case studies, the authors analyzed and categorized the students' responses to the follow-up questions (see part 2 of the pretest and posttest in the appendix). Each category was then labeled as "relevant/applicable" to the situation or as "irrelevant/not applicable". Table IV shows percentages of student generated categories that fell into either category for each question.

Table IV. Relevance of responses to pretest and posttest follow-up questions.

Pretest		Posttest	
Question	% Relevant responses	Question	% Relevant responses
#1	45	#1	90
#2	50	#2	71
#2a	59	#3	75
#2b	91	#4	100
#3	77	#5a	75
#4	100	#5b	40

On average, the percentages of "relevant/applicable" categories generated from the students' responses to the posttest questions were higher than those for the pretest. One exception is question #5b of the posttest, in which students were asked to identify what rights a research advisor has over his/her research student's work. Two-fifths (40%) of the students responded that the research advisor has rights to everything that the student has produced. Another 20% responded that the university has rights to everything that the student has produced. This will obviously be an area that is discussed in greater detail the next time that the course is offered.

One weakness of the responses to the posttest questions is the inconsistency in the student's abilities to frame their arguments. In many cases the students immediately assume a "side" of the argument and fail to address the nuances of the situation. This observation suggests that we should introduce a formal framework for analyzing an ethical situation into our course,

something we have not done in the past. For example, Michael Davis, professor of philosophy and senior fellow at the Center for the Study of Ethics at IIT, has published a seven-step method for ethical decision making.[4] This framework could easily be integrated into our course.

In addition, it would be enlightening to compare the student's responses to these ethical situations to the responses of experienced biomedical engineers and scientists. In the next iteration of this course data will be collected from experienced faculty and researchers in an attempt to measure whether students' responses migrate toward those of experts after participating in this course on research ethics.

This ethics course was delivered one hour per week as part of a 10 week summer REU program. However, we think it could be logically extended to a semester long course or as part of training required for other, more sustained undergraduate research programs. In this form the topics could be expanded upon with a greater number of case studies and more in depth discussion. In addition, in a semester long program students could be asked to pursue a more in depth literature search on the topics and more additional pedagogical methods could be explored.

4.0 Acknowledgements

We would like to acknowledge support from the National Science Foundation (Grants 0852048 and 0933810), the Pritzker Institute of Biomedical Science and Engineering, and a generous donation from Mr. Edward Ross for support for this program.

5.0 Bibliographic Information

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Appendix

Introduction to Research Ethics

Course Instructor: Eric M. Brey, Ph.D. (brey@iit.edu)
Vivian Weil, Ph.D. (weil@iit.edu)
David Gatchell, Ph.D. (dgatchel@iit.edu)
Kelly Laas (laas@iit.edu)

Catalog Data: N/A

Catalog Description: N/A

Topics Covered:

1. Introduction - June 2
2. Policies & Principles (Codes of Ethics-lab/institution, grievances) - June 9
3. Advisor/student relationships – June 16
4. Issues facing women and underrepresented groups – June 23
5. Intellectual Property Authorship – June 30
6. Conflicts of Interest – July 7
7. Statistics/bias – July 14
8. Animal Studies – July 21
9. Human Studies – July 28

Prerequisites: None

Textbook None

Reading Material: Occasional handouts

Website openseminar.org/ethics
Student entrance
Institution: Illinois Institute of Technology Research Experience for Undergraduates
Professor: Eric Brey, Ph.D.
Course: IIT: REU: Research ethics

Assignments Student groups are assigned to cover each topic. The groups will provide a presentation on the topic and guide class discussion. They should provide the class with a two page summary of their topic. The student groups will be expected to read sections on the openseminar.org/ethics web course, discuss the topic with graduate students in their lab, get input from their research mentor and Dr. Brey or Dr. Gatchell, and to interact with members of the Center for the Study of Ethics in the Professions (Vivian Weil and Kelly Laas) to research the topic. Each group should:

- present a summary of the topic with a handout/outline
- provide a case report that exemplifies issues that may be encountered

- develop assessment methods to be used as pre and post tests for the topic

A draft of these three items must be submitted to Dr. Brey, Dr. Gatchell, Professor Weil, and Ms. Laas by **noon on the Monday prior to the class meeting time**.

Course Schedule: The course meets one a week for sessions that last one hour. The course is offered as part of the summer REU program. Wednesday, 4-5 PM, WH 315.

Student Learning Objectives (SLOs):

1. Upon completion of this course, students will be expected to be able to discuss ethical issues in laboratory research and identify problems that can occur when research is conducted without adherence to ethical guidelines and principles.

Prepared by: Brey, Gatchell, Laas, Weil Date: 6/2/10

Ethics Pre-Test
PART 1

A new graduate student, Jill, has started working with Dr. Brey in pursuit of her Ph.D. The student is paired with a 5th year graduate student, Brian, to learn research techniques used in the lab. Brian is writing his thesis on a new biomaterial technique he developed for encapsulation of islets for treatment of type I diabetes. As Jill is learning the technique she is getting results that are inconsistent with a publication from Dr. Brey's lab. Brian, Dr. Brey, an undergraduate in the lab, and a collaborator from another institution are all authors on the publication in question. Jill mentions her concerns to Brian, but he says she just has not mastered the technique so her results will improve as her technique improves. He says the experiments have been repeated many times as she can see in his lab notebook. After examining Brian's lab notebook, Jill is still not convinced of his results.

Describe potential issues in research ethics that can arise from this situation. For each issue describe who may be impacted by these issues and how Jill may go about addressing the issues.

Ethics Pre-Test
PART 2

1. What repercussions may there be if Jill challenges Brian's results to Dr. Brey?

2. The paper is already published, so what options are there in terms of the manuscript. Is there anything they can do?

    a. How can Jill find out what the options are?

    b. Who is responsible if the results are determined to be false?

3. If Jill brings up the issue to Dr. Brey and he sides with Brian, what can she do?

4. How may Brian's lab notebook help with issues encountered in this scenario?

Ethics Post-Test
PART 1

A graduate student has been working in a lab with Dr. Brey for 5 years. The student has defended his/her thesis and graduation is coming around. As the student is searching for another position, the student asks Dr. Brey to write a recommendation letter. That letter helps the student land a new job. Before the student graduates, Dr. Brey provides the student with a list of materials (such as lab notebooks, data, files) that the student may not take with them. In addition, he provides a list of research areas that he expects the student not to work on in the future. He asks the student to sign the document.[1]

Describe any ethical issues in this situation and how the student may go about resolving thos issues?

Ethics Post-Test
PART 2

1. Do you think the advisor has the authority to require the graduate student to:
    a. Leave research materials behind?
    b. Not perform research in certain areas?

2. Does the nature of the student's new position influence the rights of the advisor? would this be different if the student was going to a university or an industry job?

    a. What about the other way around, if the student is going from an industry job to graduate school and industry asks them to sign a similar form?

3. If the student has an issue with what the advisor, where would they go? who do they talk to?

4. What repercussions may there be if the student challenges the advisor's rights to request these items?

5. When you leave this summer program, what materials, data, and/or intellectual property do you have rights to? Can Dr. Brey use all of them?