

Integrating Ethics in BNG-371: Cell Tissue Material Interactions

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Introduction:

BNG-371: Cell Tissue Material Interactions is a junior level course in the Bioengineering major sequence. This course examines the body's wound healing response and explores how implanting a biomaterial can affect this response as well as how this response affects the function of the implant. Every Friday throughout the term, the students were required to read and present journal articles that related to the topic being discussed in lecture that week. Several of the articles involved the use of animal models for *in vivo* studies. There are several ethical issues involved in the use of animals for scientific research. A chapter of the textbook explores the various levels of experiments that must be done to prove biocompatibility, safety, and efficacy. The levels range from *in vitro* bench top experiments to clinical trials. Each of these levels has their own ethical issues. I taught this course in the fall of 2008 and the students were very curious about how clinical trials work and what is involved in doing trials. It was clear that an ethics module would fit perfectly into this course.

Course Structure:

Throughout the course, we discussed some of the ethical issues related to animal models in scientific research. Most of the journal articles that were read and presented by the students involved animal models. Each week the same discussion point was raised, why use this species of animal? Why were x number of animals used? How were these experiments approved (i.e. through an IACUC)? The students mainly drove these discussions and I would direct their attention to sections of the article that discuss the approval and care of the animals. We then spent a week of the course discussing the experiments that must be completed before going to an animal model and the regulations involved in using these animals. We talked about the choice of the animal model and read articles that studied the viability of several animals as models for various wound healing processes. We discussed the advantages and disadvantages of these models in terms of predicting a patient's response to the implant. I encouraged the students to explore the websites and publications of such activist groups as PETA. We discussed some of the issues raised by PETA in class, however, I stressed to the students that with FDA regulations, animal testing is a requirement.

For five classes we discussed the government regulations involved in getting a medical device approved for use in humans. Throughout the term we discussed the necessity of animal studies in the device approval process. The final stage of device approval is clinical trials. After consulting with a faculty member in the bioethics program of the Union Graduate College, I distributed a few chapters discussing the characteristics of clinical trials and the ethical issues related to these characteristics. We also read a fascinating piece from the *New England Journal of Medicine* on ethical issues related to the "outsourcing" of clinical trials to developing nations. The students were responsible for reading the provided material. I used this material as a basis to start discussions in class on some of the issues that were raised in the readings and let the students drive the discussion with a little push here and there from me.

The students were required to turn in a 5-page paper, which counted for 10% of their grade. The assignment was to discuss the advantages, disadvantages, limitations, and ethical issues pertinent to *in vivo* animal tests and clinical trials in evaluating biocompatibility of implant materials and devices.

The students used the materials provided in class as well as animal activist websites to get another point of view when forming their thoughts.

Challenges and future directions:

The main challenge was that I had to learn about clinical trials, as this was a new topic for me as well. The students seemed more interested in the animal research than the clinical trials. I believe this is partly due to a lack of understanding about clinical trials where as animal research is easier to grasp in terms of the regulations. I am very pleased with having this module in the class and I believe the students found it very interesting based on their papers

and the class discussions. I look forward to teaching this module again in my course next winter. I will do a few things different. One, I will spend more class time discussing clinical trials. I hope to have guest speakers with better expertise in clinical trials and animal rights issues. I have also requested more materials from publishers so I can provide some case studies and more in depth material to the students. Overall, the field of bioengineering is wrought with ethical issues and I am very pleased to have the opportunity to discuss some of these issues in my course. I look forward to incorporating ethics modules into other bioengineering courses that develop as the major grows.