Ethical Issues in Invention, Innovation, and Entrepreneurship

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Abstract

Ethics and Policy is one of three major teaching divisions within the Stanford University Biodesign Program, along with Innovation and Technology Transfer. We have addressed our obligation to educate our students about the ethical implications of developing technologies by course work and by creating case studies with defined scenarios that encourage students to consider real-life situations and respond to challenging ethical dilemmas. Personal ethics surrounding working in interdisciplinary teams in new environments are many and varied. Ethical issues in medical innovation and medical investigation have special legal implications. Conflict of interest is much discussed in the media and it is a topic that students need to understand in the personal and educational contexts, but they also need to develop sensitivity to conflict of interests for their future careers. This paper will describe the ways in which Biodesign approaches ethics within the biomedical technology innovation setting.

Introduction

We believe the role of innovators and inventors in our society requires us to teach ethical decision making as part of the educational experience. Many students do not appreciate the various choices they make unconsciously, and daily, on the basis of their backgrounds and training. Medical innovators have a special obligation to understand the many ethical issues they must deal with in the development, pre-clinical and clinical testing, and marketing of their potential products.

The Biodesign Program within Stanford University has sections teaching the basics of Innovation and Technology Transfer. It also has designated a section on Ethics and Policy that has begun creating educational methods, over the past five years, for addressing ethical issues pertinent to the students' behavior during their time within the program and throughout their careers. This paper describes the main aspects of the approaches taken so far in the Section on Ethics and Policy.

General and Specific Areas of Attention

There are a multitude of approaches to the process of innovation and invention by an individual or by a team. The Biodesign Program within Stanford University (http://biodesign.stanford.edu/bdn/index.jsp) includes several major efforts to teach a specific method of medical need identification, concept development for solutions to the needs, creation of prototype products, and understanding both protection of intellectual property (IP) and how business considerations affect the potential for the invention or product to succeed in the area of medical technology.

The Biodesign Program includes courses, fellowships, seminars, and one-on-one training. One effort involves teams of graduate students from engineering, medical, and business backgrounds engaged in the full process being taught over an academic year. Another effort includes a class, over two academic quarters, in which teams select and adopt previously defined needs and continue from there to the process of finding solutions and creation of prototype products, understanding both protection of IP and how business considerations affect the potential for the invention or product to succeed. Throughout and within this framework we attempt to highlight the choices that are made and their ethical implications.

Students are encouraged to think of the goal of making ethical decisions as the path to doing the "right thing" in a given situation. The need to make decisions means there is more than one choice available. Very often the chosen course includes the loss or mitigation of the possibility for taking the alternative choice, and this may mean a "conflict of interest" for the decision maker. Conflict of interest arises when "one of an individual's personal interests is at odds with another of that individual's personal interests," or "when an individual's personal interests are at odds with the interests of others."[1] Because the innovation process is laden with

decisions, conflict of interest is inevitable. Realistically, the objective of any innovator or entrepreneur should not be to avoid such conflicts, but to ethically address and resolve them when they arise.[2]

There are several general principles that are explicitly discussed as the basis for ethical decision-making within our training program. These include:

- *Truthfulness*: Being clear and honest in all thoughts and communications.
- *Fairness*: Dealing with all people and projects in a just and even manner.
- *Respect for persons*: Recognizing the autonomy of others, their freedom of choice, and their right to act or refuse to participate in an activity.
- *Confidentiality*: Understanding what information is privileged and being rigorous about protecting such data from inappropriate use.
- *Beneficence*: The obligation to do no harm to others. In the medical field, this mandate extends to maximizing benefits while seeking to minimize potential harm.

In addition to the general principles enunciated, multiple concise scenarios have been created to bring up specific points for consideration by the students with discussion led by various people experienced in the field. (http://www.stanford.edu/group/biodesign/cases/cases.html)

Areas for Discussion

The optimal interaction of team members requires recognition of issues of respect for individuals, truth-telling, and acceptance of differences in background knowledge, talent, and skill-sets. The success of the team, rather than success of the individual apart from the team, may be a new concept for some of the students who have been competitive with others in order to achieve their current place in the university. The practical benefit of adjusting to these factors in the short-term can be emphasized. However, building recognition of personal integrity within a team is most important as a critical aspect of a lifelong career.

Other scenarios highlight engineering team members' conduct in hospital settings and help students understand their place within the delicate environment of personal patient privacy, confidentiality of health information (including the HIPAA regulations), and interaction with the physicians responsible for the patients they encounter.

The students are asked to make choices around a scenario of attribution of ideas during invention, with the expectation of eventual financial consequences to them. Other exercises focus on clarifying legal and ethical aspects of intellectual property (IP) creation. One of these cases has the students consider the proper involvement of faculty in the innovation and invention process of the students, both from an educational perspective and regarding inclusion on the IP generated by the team. The degree of confidentiality or "stealth" around needs and solutions during the early stages of innovation in the otherwise open academic setting is the focus for another discussion. Interaction with mentors and coaches from industry who are intimately involved in the teaching and learning process but are not part of the academic faculty bring problems and choices for the students regarding information sharing and inclusion in IP.

Cases involving the relationship of academic faculty, staff, and students with the medical device industry are available as well. This interaction has been prominent in the lay and medical press and deserves attention for those who will eventually work in this industry.

The scenarios are presented in concise form and include a series of questions to be addressed in discussion. Specific answers are not given as part of the cases because the discussion that occurs in this context should bring out various opinions of what is "right" in a certain situation. Arguments about the approaches and answers provoked by this exercise are participatory educational experiences for the individuals involved. This also permits the discussion leader to know the level of understanding of the students and tailor the discussion to bring out points they may have missed. There is often more than one "right" answer for an individual and for a team, depending on the situation, and thus a single correct answer often is not favored over a list of potential resolutions for the dilemmas presented. Highlighting the differences of opinion and the ultimate need for a choice to permit further action helps students understand both team consensus building and ethical decision making.

Example Case

You are developing a tool used in hip replacement. A disposable device is the best business model in the US, yet you know doctors in developing countries are likely to reuse the device against company recommendations. Of materials A and B, A is less expensive but B will not weaken when exposed to the heat and pressure of autoclave sterilization.

- Which material do you choose: A or B?
- Why do you make that choice?
- Should you sell the device for more or less to doctors in countries that will reuse the device?
- What labeling of the device is appropriate from your company's perspective?

These cases create scenarios of practical situations in which the students may find themselves now or in their later positions in the "real world." Some of them are available through the Biodesign website. (http://biodesign.stanford.edu/bdn/resources/ethicscases.jsp) The areas in which we have tried to create a framework for consciousness-raising and discussion are shown in Table 1.

Ethical Issues in Human Clinical Trials

Students are encouraged to consider patients and testing of their devices on patients from the outset of the Biodesign Program process. Ethical considerations and the ability to minimize and manage conflicts of interest are especially important when it comes to the testing of medical technology in human subjects. *The Belmont Report* is a statement of ethical principles and guidelines that can be used to help resolve these sorts of ethical problems.[3] The development of this report stemmed from the passage of the National Research Act, signed into law in 1974. It was published on April 18, 1979 and remains the definitive resource on the subject today. This act resulted in the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was charged with defining the basic ethical principles that should guide researchers in their justification and practice of involving human subjects in clinical research. This report and its specific points are emphasized in lectures and discussions of cases in the format of scenarios noted above. In addition, the inherent bias associated with various financial and non-financial conflicts of interest is highlighted as a potential obstacle to objective evaluation of invented technology. This is of special importance when the welfare of patients is involved and when there is unknown benefit, but likely risk, to the study subjects enrolled in a clinical investigation.[2]

Teaching Venues

Formal lectures with case discussions are part of the Biodesign classes. Individuals from the program present similar talks for several of the Bioengineering and Mechanical Engineering classes. Some of the medical departments within the School of Medicine have requested talks on these subjects tailored to the issue of physician conflicts of interest and the interactions of physicians with industry. In addition, Biodesign faculty provide individual counseling to students as they encounter issues throughout their training. In fact, these sessions have provided the general basis for several of the case scenarios presented in the classes for discussion.

Conclusion

Evolving experience with attempts to include ethical decision-making within the context of a program for teaching a process of invention and innovation has led to multiple approaches to this goal. The students have been extremely appreciative of the methods developed so far. Some students have had no prior experience in formal discussion of ethical issues in decision-making. The evolution of these methods has depended on the students' reaction to the various techniques developed. Open-ended discussion of "real-world" scenarios has been the most stimulating exercise for both the students and the faculty. The Section on Ethics and Policy expects to continue development of this effort both in response to our own belief that it is appropriate in this program and because the students have been so appreciative of it.

Table 1.

Individual behavior
Working in teams
Choices in prioritizing medical needs
Choices in prioritizing solutions
Choices in product design
Confidentiality in the open academic setting
Interaction with patients
Conduct as part of a medical team
Ethics of pre-clinical research
Ethical issues in clinical investigation
The academic-industry interface
Choices for licensing versus company building
Fund raising for the new idea
Dealing with the financial community
Consequences of device failure in patients
Dealing with device failure in patients
Communication with the medical community/customers

References

1. Thompson, D.F. 1993. Understanding financial conflicts of interest. *New England Journal of Medicine* 329:573-6.

2. Popp, R.L., and L. Denend. 2007. Ethics and Conflicts of Interest. *Stanford University Graduate School of Business cases*.

3. The Belmont Report. 1979. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Accessed 9/24/07, at http://ohsr.od.nih.gov/guidelines/belmont.html.)