# Current State of Bioethics Relating to Biotechnology for Engineering Education

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## Abstract

Biotechnology provides a wealth of products which improve the lives of many individuals. Some improve the quality of life of the person while the others extend their lives. Another biology oriented research area is synthetic biology, which is a sub-category of biotechnology. Products from synthetic muscle tissue and medications to biofuels are the subjects of research today. Each product developed has to be evaluated as to whether it can be produced sustainably and economically while taking into consideration the effect on the environment and protection of human rights. With the introduction of new products and technologies, bioethics is evolving, which means the educational community has to be up to date with the current bioethical issues and accepted practice in order to prepare the engineering students to be involved in research as a student and in industry. The present study will investigate bioethical issues associated with biotechnology and synthetic biology. It will also touch on how these issues are handled globally.

## Keywords

Biotechnology, Synthetic Biology, Bioethics, Recent Developments, Health and Environment, Engineering Education.

## Headings

## 1. Introduction
### 1.1 General Background

Biotechnology is "the study and manifestation of living bodies or their components (e.g., molecules, organs, cells, and tissues) in order to improve their living conditions." [1] Synthetic biology is a sub-category of biotechnology and is the "designing and combining of biologic molecules such as deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins in order to provide a better understanding of the biological phenomenon and produce biological systems with certain functions." [2] Synthetic biology differs from the biological sciences in that in the biological sciences the cell is studied in order to understand how it works and in synthetic biology they design and create a new cell. [2] Associated with these areas of research are concerns about bioethics, responsible conduct and safety.

Bioethics is "a relatively recent field of academic inquiry that deals with the ethical, legal, social and cultural implications of the biosciences and their application in biotechnology." [3] There are inherent safety risks involved with biotechnology and synthetic biology because these areas of research involve designing new materials which have the potential of having unintended

consequences. This is especially true in synthetic biology since this involves manipulating the most elemental level of materials.

## 1.2 Historical Perspective of Bioethics

The World Medical Association adopted a form of the Hippocratic Oath called the Declaration of Geneva for all candidates wanting to join the medical profession in 1948 at the 2nd General Assembly of the World Medical Association, Geneva, Switzerland. [4] Although medical ethics has its roots in ancient Greece with the Hippocratic oath, bioethics came to the forefront as an issue at the end of WWII with the trial of 23 doctors for human experimentation in the concentration camps. The result of the Nuremberg Trials was a set of research ethics principles for human experimentation established in 1947 which was called the Nuremberg Code. The Nuremberg Code was meant to be used by countries as a guideline for their laws concerning bioethics. This code and the subsequent World Medical Association Declaration of Helsinki in 1964 is the basis for the ideas of informed consent, beneficence and minimizing the risk to the research subject in research involving human subjects. The Declaration of Helsinki states that "it is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research." [5]

In the United States (U.S.) between 1947 and 1979 research involving human subjects without their consent or with questionable consent continued in spite of the code of bioethics adopted in this country to address areas of ethical concern. A few examples of this include research into treatments for hepatitis A[6], sexually transmitted diseases,[7] schizophrenia,[8] radiation exposure [9] and cancer studies. [10] The research subjects included prison inmates, mentally disabled children, hospitalized mentally ill and the elderly. In 1974 a story by a reporter outlining research initiated by the U.S. Public Health Service in Macon County, Georgia, which was called the Tuskegee Study, [11] caused public outrage over the unethical treatment of the human subjects in the trials. The Tuskegee Study research started in 1932 when there was no definitive treatment of syphilis but continued until the story broke in 1972 even though penicillin was developed as a treatment in the early 1950's. In the study, 412 poor African-American men with syphilis were followed and left untreated while 204 men free of the disease were used for comparison in order to research and document the progression of the disease over the lifetime of the subjects. The subjects were deceived in order to get them to consent to participate in the clinical research and they were denied treatment even after an effective treatment was developed. [11]

As a result of the public outrage, the National Research Act which was passed in 1974 created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission would regulate research conducted by the then Department of Health Education and Welfare (HEW) and identify basic ethical principles to protect human subjects in research. The Belmont Report summarizes the ethical principles developed by the commission which are Respect for Persons, Beneficence, and Justice which should be applied with respect to the requirements of Informed Consent, Assessment of Risk and Benefits, and Selection of Subjects. [12]

In 1981 the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) revised their regulations to reflect the recommendations in the Belmont Report. The result was what is called the "Common Rule" which involved 15 Federal

departments and agencies and was published in 1991.[13] Under the common rule clinical research was defined and regulations were outlined. All research falling under the "Common Rule" was to be overseen by Institutional Review Boards.

The Council of the National Academy of Sciences formed a committee on the conduct of science and reported their findings in 1989. Their report, On Being a Scientist,[14] offers guidelines on how to conduct research using scientific methods while attempting to accurately gather facts and report them without prejudice. This can form a basis for a beginning researcher to develop and maintain responsible standards for scientific conduct.

## 2. Global Evolution of Bioethics

In the U.S. oversight of clinical research is accomplished through Institutional Review Boards which are responsible for making final recommendations regarding patient care ethical issues and ensuring that clinical research complies with the basic ethical principles. All research supported by a government agency which falls under the "Common Rule" is required to have an Institutional Review Board which complies with the Common Rule to review its research[15]. Although bioethics is more regulated and Institutional Review Boards oversee clinical research, there are still issues arising. It is logical to go to the areas where a condition is prevalent to research the signs, symptoms and progression of the condition as well as its effective treatments. This results in poor and impoverished nations being the subject of the research. This in itself can be looked at as exploitation and the ethics of it can be questioned. One such situation occurred from 1991-1993 in sub-Saharan Africa and Asia in the research of HIV treatments to prevent transmission of HIV to fetuses in pregnant females.[11, 16, 17] The double-blind clinical trials conducted were placebo-controlled studies which would mean giving a placebo to a segment of the research subjects. This would insure that treatment would be withheld from a percentage of the research subjects and their babies would not benefit from the treatment if effective. The reasoning of such a research project is that without the research there would be no effective treatment to prevent or reduce the incidence of infected fetuses, and therefore those babies who became infected with HIV through the pregnancy and/or breastfeeding would have been infected anyway. In this study, when the treatment was shown to be effective, further research which concentrated on the dosage and regimen of treatment did not involve placebo-controlled studies.[18]

An article in the New England Journal,[11] which criticized the HIV study as unethical resulted in a worldwide debate. The Global Forum on Bioethics in Research (GFBR) was formed by several organizations such as the National Institutes of Health, the Rockefeller Foundation, the Medical Research Council (MRC) United Kingdom and the MRC South Africa. The GFHR provided a forum between 1999 and 2008 for discussing the ethical issues associated with research conducted in developing countries. It was re-launched in 2014 to provide somewhere for individuals in low- and middle-income (LMIC) countries to bring their bioethics concerns regarding research in their country.[19]

Some countries are still developing their bioethical codes and regulations. In Iran biomedical research began in the 1970s but was halted in 1978 through the 1980s due to the Islamic Revolution and then the Iran/Iraq war.[20] In the 1990s research began again. By the late 1990s clinical research had reached a fast pace and bioethical concerns were emerging. A study of

research proposals [21] showed that only 1% of the studies investigated mentioned ethical risks, and in only 11.8% were those participating aware they were participating in clinical trials. Of these trials, 32% were placebo-controlled. The cost of the biomedical research interventions that the participants were subjected to was paid for 80% of the time by the participants. When the results of the study were published in 1999 the National Research Ethics Committee was established. [20] In 2004 the Medical Ethics and Medical History Research Center (MEHR) was established. MEHR developed the National Ethical Guidelines on Biomedical Research. The development of biomedical research oversight in Iran was very similar to that experienced in other countries. Hopefully as this area continues to develop they will be able to benefit from the experiences of other countries and avoid further duplication of the painful learning process those countries experienced.

Research in synthetic biology is also being conducted in Japan, although it is not always referred to as this because the term is not widely accepted. The Japanese Society for Cell Synthesis Research was founded in 2007 and included in its purpose was the study of ethical and safety issues associated with this area of research. The organization promotes discussion and exchange on the subject of social and ethical issues among researchers internationally and in the Japanese public sector. The existing "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" has been satisfactory in regulating synthetic biology up to this point, but as this area of research progresses with new developments in the field, new regulations specific to this area of research are expected to be necessary.[2]

## 3. Current Biotechnology Research and Bioethical Issues

Over one hundred billion U.S. dollars are spent each year on biomedical research as shown in Table 1. Some research is funded by industry and some through government sources. Biotechnology is expected to produce novel answers to societal needs. Biotechnology can increase the food supply by designing disease resistant strains of crops. It can provide new sources of energy, new medications, and treatments for disease.[22, 23] It is also a potential source of disaster, either accidentally or purposefully by terrorists, from the development of an organism deadly to the environment, animals, and humans.

**Table 1: Expenditures in Biomedical research in 2012 in billions of U.S. dollars.[24]**

| Country | Total | Country | Industry |
|---|---|---|---|
| **United States** | **119.3** | **48.9** | **70.4** |
| **Canada** | **5.3** | **3.3** | **2.0** |
| **Europe** | **81.8** | **28.1** | **53.6** |
| **Asia-Oceania** | **62.0** | **19.3** | **42.7** |
| **Total** | **268.4** | | |

Biotechnology has the potential to develop a new energy source in biofuels that will comply with the new carbon emissions and carbon "foot-print" regulations. Biofuels are considered carbon neutral because their carbon content is being recycled by the plant process. Biofuels have the

capability to replace the current carbon fuels and would be sustainable with an endless supply, but would not deliver the same BTU values as coal or oil. There are ethical problems associated with biofuels. The use of corn for biofuel decreases the corn supply for food and results in increased food costs.[22] In the U.S. over 30% of the corn crop was being converted into biofuels in 2005.[23] Another avenue of biofuel research is algal energy for biofuels. This source of biofuel would not directly affect the food supply but could indirectly affect it by taking up acreage that would have been used for food production. If acreage not suitable for agriculture is used it could result in reduction of biodiversity by deforestation and reduced wildlife habitat. [22] Currently the rainforest is being razed for agricultural purposes.

Synthetic biology has its own ethical concerns. Though presented by some as being similar to building with LEGO blocks, the process is much more complex and less controllable than that. It has also been likened to programming a computer which is possibly more accurate than the LEGO blocks analogy.[25] Synthetic biology involves taking the building blocks in the biological world which randomly associate themselves in a highly predictable way and attempting to realign or remove and replace segments through controlling the process. In 2011, biologist J. Craig Venter created the first viable bacterial cell that was designed in a lab by digitally writing its genetic code and synthesizing it in a laboratory.[25] Science is advancing with the goal of being the first, for instance, to engineer skeletal muscle that can be used to repair damaged human limbs [26] or develop a new strain of fungus resistant corn.[27] The behavior of a synthetic program cannot be completely and reliably predicted. Therefore, in designing a synthetic genetic program there is the possibility of unintended consequences. This causes concerns about the creation of organisms that may be harmful for humans and the environment and could potentially have devastating effects on the environment, wildlife and human populations. Therefore, an ethical research scientist takes measures to protect researchers and the environment from exposure.[2] The risks of exposure and contamination have to be considered in designing the research project. Sometimes the ethical thing to do is not to do the research because of the potential dangers.

This technology causes concern in the public sector mainly because of what they have seen in science fiction films. Public concern is also due to a lack of information or a lack of understanding of the available information on biotechnology and synthetic biology.[25] In order to address public fears educational programs should be developed to inform the public of what safeguards are in place to protect them and the environment.[12] Public education programs and discussion forums with panels of experts can help disseminate the required information to the public and answer their questions. Without adequate education they will be motivated by their fear and will probably resist the technology.[4]

The National Science Foundation funded the Synthetic Biology Engineering Research Center (SYNBERC) in order to responsibly advance synthetic biology. Their three-fold mission is: [28] 1) to develop the foundational understanding and technology needed to increase the speed, scale, and precision with which we design and build biological solutions; 2) to train a new cadre of engineers who will specialize in synthetic biology; and 3) to engage policymakers and the public about the responsible advance of synthetic biology.

As the area of bioethics matures and as policies and principles are developed, the scope of ethical concerns broadens. For example, in the past outside interests of the researchers were not required to be reported. It was left up to the researchers to determine if there were any conflicts

of interest, but in today's environment research scientists are being asked to report their outside ties to industry and who their investors are.[29]

## 4. Implications for Higher Education

Seeing the complexities of bioethics and the historical perspective of the difficulty of research scientists in viewing their research in a bioethical and responsible manner, it becomes clear that training and education of the future engineers, researchers and research scientists in critical bioethical decision making are vitally important in order to ensure clinical research and other bioresearch will be conducted ethically. Although regulations and oversight are in place, it is the responsibility of the research scientist and researcher to comply with ethical principles and give safety top priority.[14] Future researchers and engineers must be trained to maintain standards of ethical scientific conduct.

The National Institutes of Health (NIH) has included in their requirements for institutions receiving Federal funding that students receive ethics training. They have also identified case studies and small group discussions as the best way to teach these principles. Another requirement is that there be at least 8 hours of face-to-face instruction because it has been identified as a necessary component of training. The National Academy of Sciences has identified personal contact with more experienced scientists as a necessary component for junior researchers to learn a code of professional conduct.[14] With these things in mind an institution would have to develop a program for ethics education. There is a source of curriculum assistance available at:
http://www.fic.nih.gov/RESEARCHTOPICS/BIOETHICS/Pages/teachers-students.aspx.

Wichita State University, in Wichita, Kansas, has a general ethics offering required for all engineering students which conforms to ABET requirements. The catalog description of what is taught in this class is: "professional responsibility and integrity, whistle-blowing, conflict of interest, ethical issues in engineering consulting and research, engineering and environmental issues, and engineering in a global context." There is no offering for an ethics class which covers the specific areas of bioethics or nanotechnology ethics which are both areas of concern in relation to the environment and public safety. Ethical issues associated with these areas have historically been addressed in the research setting between graduate students and the more experienced research scientists/professors. Future research scientists need to be trained in how to address ethical issues before encountering these situations in order to resist industry and outside funding source pressures for quick results.

One way to assist the researcher in making responsible and ethical decisions when dealing with complex, difficult ethical dilemmas is to provide them with an ethical analysis tool. Two examples of analysis tools used for this purpose are the Four A's and the Four Quadrants or Four Boxes ethical analysis frameworks. The Four A's analysis approach Acquires the facts, assembles the Alternatives, makes an Assessment of the possible solutions, and arrives at a decision on a Plan of Action[30] which is more of a scientific approach. The Four Quadrant method is more of a clinical approach which looks at the medical indications, patient preferences, quality of life, and contextual features of the ethical dilemma in arriving at a solution.[31] Teaching an analysis tool with the use of case studies can be an effective way to teach students bioethics and prepare them for the issues they will face as research scientists and

engineers.As biotechnology research is conducted in LMIC countries it is important that the stakeholders in these countries be included in discussions of bioethical policies to provide protection of their interests. In order to accomplish this, LMIC countries must have personnel trained in ethics principles to facilitate the discussion. NIH's Fogarty International Center has provided grants to establish ethics training programs in international research ethics. An example of the success of these ethics training programs is their training programs in Latin America and the Caribbean. In 1991 there was little oversight of clinical research or protection of research subjects, and international principles for bioethical research were not being applied in research programs. Four bioethics programs were initiated in that part of the world. One was developed in Latin America, one was coordinated from the U.S. in conjunction with Latin America and two were coordinated from the U.S with the cooperation of Latin American institutions. These programs have been very successful in changing the research environment in the countries through distance learning and online components provided by U.S. educational institutions.[32]

The success of the NIH's Fogarty International Center programs show that ethics programs in the U.S. should be developed to include a world view of bioethics in research. Students must be taught bioethics from an international perspective. More and more students are being employed outside the U.S. in these LMIC countries and can provide needed ethical expertise to protect the interests of those countries in policy development of research entities and local governments.

## 5. Conclusions

Biotechnology is an emerging technology, and based on the technological developments it will be one of the most studied topics in the world. This is a valuable tool to make many new advancements on environment, health and science. In the present study, biotechnology, synthetic biology, bioethics, and their major impacts on human health and environment have been discussed. The primary issues associated with bioethics include current rules and regulations, historical prospects, future developments, legal limitations, morality, religious aspects, and safe practice and safety training of the engineering students. It is reported that many biotechnology products and practices are completely safe, whereas others can be highly toxic and harmful, resulting in serious diseases to humans, as well as surrounding environments. Bioethics mainly deals with all of these biotechnology related issues in order to create a safer work environment for students, scientists, engineers, health professions, and other individuals directly and indirectly participating in biotechnology research, development, and education.

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