In this lecture, I am going to present an overview of ethics in medical research. I will present a framework for understanding medical ethics as well as discuss several studies with ethical problems.

Belmont report is an important report developed by a committee of researchers, lawyers, government officials, lay people and others to address research regulation. This report was an amazing product and I have included a video with a description of the reason for this and the work done. There is also a link to the report itself. As you go through the IRB process and CITI training USF at USF, you will learn about the Belmont Report. Take some time now to click on the link to the report. This report led to the development of medical ethics that still directs what we do today.

http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Ethics refers to the norms for conduct that distinguish between acceptable and unacceptable behavior. Our ethical viewpoints are shaped by many factors, our culture, family and religious values, personal experience, among others. There are two general frameworks for ethical decisions. The first deontological has a set of clear rules that indicate whether a specific behavior is always right or always wrong. In contrast, in a situational ethical framework, the ethics of a behavior depends on the end result, a “the end justifies the means” construct. Let me give you an example. In the deontological framework, one would say that killing someone is wrong. Many of us would agree with this statement. But in the situational framework, one might feel that...
killing is usually wrong but there are times when it is not: e.g., at war, assisted suicide, abortion, or abortion when a fetus has a serious health defect.

There are four key principles in medical ethics: beneficence which means that we need to do good, non-maleficence which refers to doing no harm, respect for autonomy in which an individual is able to make his/her own decision, and justice in which the benefits are equally distributed across all groups. Click on each arrow to see a description of each principle.

Beneficence refers to the principle that doctors and researchers need to act in the best interest of their patients or research subjects. It is unethical to withhold a treatment that is beneficial. This would have implications for randomized clinical trials in which part of the study population receives a placebo. Thus, placebos are only ethical when we are doing a trial of a treatment that we do not know is effective. In fact, many of these trials have set stopping points in which the data are examined to see if there is enough evidence that the treatment works that the trial should be stopped and all participants given the treatment. This happened in the trials of AZT in pregnant women to prevent the transmission of HIV to their children. The evidence was so strong that this drug worked that the trial was stopped early and all women were then given the drug. Similarly if a trial shows increased risk from a medicine, it may be stopped early to protect people. We also have given medical treatments at the time that we thought were good but after more research, we discovered they were not, for example high rates of tonsillectomies among children. This principle also speaks to the importance of evidence based medicine and the need for research studies.

Autonomy refers to the right of people to give consent to any treatments or research. The belief is that people have the right to make their own decisions. But in order to make a decision, people need to have sufficient information. Thus withholding information from study subjects violates the principle of autonomy. You will see this happen repeatedly in unethical studies and I will show you some examples. So how do we have a placebo trial and still respect the autonomy of the study subjects? The way this is done is that when people
enroll in the study they are told that there is a placebo arm and that they will not know if they get the active medication or the placebo. So people are informed of how the trial works but they are not told that they will get a placebo. This is necessary because placebos do not have any effect if people know they are getting it. And people agree to participate knowing they may receive a placebo. The principle is the basis for obtaining informed consent from patients and research subjects.

Justice states that people should equally benefit from research. It is not uncommon that those in clinical trials may be the people who would not be able to obtain the medicine after the trial ends. In early stages of clinical trials where the risk of harm is higher, the participants are more likely to be poor, often those living in developing countries. But once a drug is approved the price may be prohibitive for the people of that country to have access to the drug. Also it is worth noting that in terms of later clinical trials, like those looking at a new cancer treatment, only individuals with health insurance are even considered eligible for the trial. Justice is often a principle that is not well met.

Non-maleficience refers to the construct of doing no harm. In clinical research, it is important that the potential benefits outweigh the risks. This can be seen in an individual basis or also in terms of benefit to society. One important step in clinical research is to clearly identify the risks to the patient, by looking at physical, psychological and social risk. Loss of confidentiality is an important risk.

- Here are some samples of cases of questionable research activities. Click on the circle to obtain more information about each case.

- You saw The Deadly Deception, a description of a study of syphilis in African American men in Tuskegee, GA. Here is a link to an apology by President Clinton. I think one of the most notable and frightening aspects of this study is how long it was continued, well after we had an effective treatment for syphilis.

- The Willowbrook School treated mentally retarded students and conducted an experiment exposing these children to Hepatitis A, This link
describes the details of this study, basically the students were exposed to Hepatitis A and there was pressure from the school to have the children exposed. Thus their autonomy was not respected and potential harm was done.

• The Milgram experiments on obedience took place to determine why people do things that are harmful to others if they are told to do so. The research subjects in this study were misled about the experiment and put in a situation in which they would feel great psychological distress. They did not have the autonomy to determine if they wanted to participate in the type of study being conducted. This video gives an example of the study.

• The Tearoom Trade was a book based on participant observation of homosexual encounters by Laud Humphry’s as his dissertation research. He was studying the actions of homosexual men from 1965-1968 who engaged in sex within public restrooms. During this study, Dr. Humphrey’s misrepresented himself as a homosexual man and misled participants about his study. An especially controversial activity was the fact that he copied license plates and attempted to follow the men after he observed them. He obtained consent from a small number of the men and thus, he did not respect the participant’s autonomy. Additionally, given that homosexuality was a crime at that time, he potentially did much harm to the men. There is a video on this study which you can watch by clicking on the start button. Plus there is a link to a short description of the study which you can see by clicking on the copy of his book.

• Radiation experiments: there have been a number of studies on the health effects of radiation, many conducted by the US military, the Atomic Energy Commission and other federal agencies. In addition, a number of workers were exposed to radiation and information was kept from them. Click on the marker to read the New York Times article on this subject.
I hope this lecture gave you a stronger sense of the importance of research ethics. Our research ethics is part of our larger ethics. If you are appalled by some of these studies, think about your own ethical choices. Just as these studies misrepresent the science, students do the same thing when they cheat on exams as they present themselves to their subjects as someone with knowledge they do not have. It is worth thinking about. It is important to realize that all researchers are responsible for considering the ethics of studies they are involved in. You can start by completing the IRB training in any institution you are attending and always think about the potential harm of any research study you participate in. I cannot stress the importance of this enough.