Human Experimentation

An Analysis of the Ethics of Human Experimentation

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Abstract

Human experimentation is an extremely controversial topic, as a result of its dark history, the many unethical experiments conducted and the severe effects that it can create. In this thesis I am addressing the stigma that is tied to human experimentation by providing evidence that it has changed drastically in the past 70 years. I dedicate a section of my thesis to the history of the reforms that are passed, because one of the most important arguments against it is the very history of human experimentation. Then there is a section that acts like a debate between two sides of the battle, and after every significant issue I provide my own opinion based on readings, studies and my own morality. I had two interviews, one with Christine Mitchell and another with Bohong Zhang. Both are professionals who deal with human experimentation on a daily basis. I analyze six articles, which are separated into three pairs of two. Each pair addresses an issue within human experimentation, and represent a side of the argument. I draw from three books for the history section as well as formulating my own opinion. Finally, with my survey and research project on sleep science, I add my own voice to the debate. The combination of everything I read, studied and performed helped create this thesis, where I provide a guide for the audience to form their own opinion on something I believe to be the most important research method ever.
Human experimentation is notorious for its dark history, and although it cannot be denied the horrors that occurred, many would argue this fact alone should not make us write "human experimentation" off as a whole. There are many arguments that say medical testing involving human experimentation is not only important to the improvement of modern science and medicine, it is essential. Human experimentation also provides the most accurate data for "effects on humans" because testing on humans and gathering results from humans means that this eliminates significant bias. However, those who oppose human experimentation argue that despite the advancements and the arguable effectiveness, there will always be corrupt human testing and the system in place to prevent corruption is at the moment basic and unorganized. In my thesis I will highlight the various arguments on both sides, and then provide my personal opinion on the issues and topics that arise. Hopefully, using both professional sources and my ideas, you, the reader, can form a less biased and more informed opinion on the topic of human experimentation.

The International Military Tribunal was established in Nuremberg, Germany, in 1945, following the Nuremberg Trials of Nazi leaders, more trials were held (Getz & Borfitz 99). One of the most important trials was "United States vs. Karl Brandt et al." or often referred to as "The Nazi Doctors Trial" (Getz & Borfitz 99). This trial happened from December 9, 1946 to July 19, 1947 (Getz & Borfitz 99). The judges and prosecutors were all American, and the 23 defendants were members of the Nazi party. They would later become infamous for the horrendous and inhumane experiments they conducted on prisoners of concentration camps. After finding 15 of the 23 defendants guilty, the Americans decided to issue a ten point code that gave guidelines and basic principles when conducting human experimentation (Getz & Borfitz 99). The Nuremberg Code is as follows (Getz & Borfitz 99):

- Informed consent should be obtained without coercion.
• The experiment should be useful and necessary.
• Human experiments should be based on previous experiments with animals.
• Physical and mental suffering should be avoided.
• Death and disability should not be expected outcomes of an experiment.
• The degree of risk to be taken should not exceed the humanitarian importance of solving the problem.
• Human subjects should be protected against even remote possibilities of harm.
• Only qualified scientists should conduct medical research.
• Human subjects should be free to end an experiment at any time.
• The scientist in charge must be prepared to end an experiment at any stage.

The next thirty years after the Nuremberg Code was established were still a time of corrupt experimentation and study. In 1966, a doctor by the name of Henry K. Beecher reported on 22 studies that had serious ethical issues, he highlighted issues pertaining to the design of the study and consent. Following his publication in the New England Journal of Medicine, a debate on research ethics began in United States. Until 1974, when Congress passed the National Research Act. This law that passed created the IRB or institutional review board. IRB's are still used by large pharmaceutical and manufacturing companies like Shire (Zhang, personal communication, April 21, 2013). IRBs conduct reviews of research specifically involving human subjects, this was the first time in history individual researchers could be denied if the approval of the medical community was not granted. The National Research Act then led to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, this committee was formed not by medical professionals but by professionals from other studies, such as lawyers, ethicists and philosophers. Advancing further in 1982, The Council for the International Organization of Medical Sciences published the International Ethics Guidelines for Biomedical Research Involving Human Subjects (CIOMS Guidelines). The CIOMS Guidelines were created for the sole purpose of guiding the research conducted by advanced countries in relation to developing countries, which was not addressed in the Nuremberg Code. In the modern day, there are many layers of protection and security defending the rights and safety of the subject, and strict guidelines controlling the researchers conduct. The FDA has a Center for Drug Evaluation and Research as well as the Office of Human
Research Protections (OHRP). But many still argue that there are some big loopholes that are unaddressed and ignored in the system.

The Declaration of Helsinki was created by the World Medical Association (WMA) in 1964. The Declaration has been revised 5 times over the fifty year period it has been around, and with every revision it becomes more progressive. It is considered a cornerstone document since the topic of ethical human experimentation became an international issue. It is described as the "most widely recognized source of ethical guidance for biomedical research". Appendix A

The Clinical Trial Volunteer's Bill of Rights states ten guidelines and rules that are meant to protect the safety of volunteers and to prevent the creation of corrupt experiments. The rights are as follows, "Any volunteer who gives his or her consent to participate in a clinical trial or who is asked to give his or her consent on behalf of another has the following rights:

1. To be told the purpose of the clinical trials.
2. To be told about all the risks, side effects or discomforts that might be reasonably expected.
3. To be told of any benefits that can be reasonably expected.
4. To be told what will happen in the study and whether any procedures, drugs or devices are different than those that are used as standard medical treatment.
5. To be told about options available and how they may be better or worse than being in a clinical trial.
6. To be allowed to ask any questions about the trial before giving consent at any time during the course of the study.
7. To be allowed ample time, without pressure, to decide whether to consent or not to consent to participate.
8. To refuse to participate, for any reason, before and after the trial has started.
9. To receive a signed and dated copy of the informed consent form.
10. To be told of any medical treatments available if complications occur during the trial.

The general principles of the Nuremberg Code and Declaration of Helsinki are understood by all researchers, and they both stand to protect the participant's rights. However, the problem with both is that the application of the guidelines and rules are often open to ambiguity and interpretation. Often leading to corrupt tests and studies. Furthermore, the general principles stated in both are sometimes not sufficient enough when dealing with certain ethical dilemmas. Situations involving children who cannot give their own consent and prisoners who might not have a choice in participation.
The words "human experimentation" cause shivers. As they should because "human experimentation" has assumed a negative connotation, as a result of the history of experimenting on humans. In the beginning of my Senior Year Project, I made a survey and published it on the Newton North High School Library website. I had two questions, and they were as follows:

1. Should consensual human experimentation be allowed?

2. Would you ever volunteer yourself for scientific experimentation?

The results were interesting, because I had expected a lot of people to say no for the first question. I intentionally phrased the question with the words "human experimentation" to demonstrate the unease people feel with the words. My results were as follows:

1. Yes: 83.3%  No: 16.7%

2. Yes: 75%  No: 25%

I began to wonder, about my results. Although I cannot prove anything, I can infer that people are slightly put off by the idea of experimenting on humans, but because I used the word "consensual" maybe it was understood that nothing was done against anyone's will. Second, people surveyed were generally uncomfortable with the idea of undergoing an experiment themselves. There are a few reasons I thought of, firstly it always goes back to the dark past, and people probably know a little bit about the history. Secondly, I think people don't quite understand the benefits of human experimentation of even the framework. Maybe people believe that the tests are gruesome or dangerous. My data could likely be biased, because it was only accessible to those who view the library website. My survey was taken by a very specific audience, also a total of twelve people took my survey making the population size pretty small. However, hopefully this thesis can also vanquish some of the bias that is tied around human experimentation, because I do very much support safe human experimentation. Appendix B
There are many benefits for an individual when they undergo a medical trial or clinical study. The most compelling reasons people chose to participate are to gain access to new therapies, to advance science, to earn extra money and to receive free medical care (Getz & Borfitz 51). However, many people misunderstand that a clinical trial is very different from medical treatment, because the test subject is not technically a patient. Under a doctor or specialist’s care, their goal is to get the patient feeling better and healthier (Getz & Borfitz 51). Contrasted to a researchers goal, which is to monitor how a subject reacts to a new drug, hopefully to see if the drug is medically relevant, useful and sometimes profitable (Getz & Borfitz 51). For those looking for new therapies, new drugs are generally much more effective than the older ones they might replace, which is extremely helpful to those who need something more potent than the conventional and traditional drug (Getz & Borfitz 51).

There are many drawbacks for the individual when deciding to undergo a medical trial. In medical trials and clinical studies there is often a control aspect built into the framework of the study or trial (Getz & Borfitz 52-53). What this means is the population of subjects is divided up between certain variables, one of which is the control. In a majority of medical trials, the control is in the form of a "placebo" (Getz & Borfitz 52-53). A placebo is sometimes but not always a sugar pill, or a pill that has no drug or ingredients that are of interest. A control is used by researchers and observers to test the psychological aspect of treatment, to see whether the pill or drug is the cure, or the thought of a pill is the cure. Many volunteers who require medical attention chose not to partake in a medical study in case they do end up receiving a placebo (Getz & Borfitz 52-53).

Furthermore, medical testing and clinical studies are designed to see the reactions to a new drug. That means many drugs could be potentially harmful to the body, and even if no direct harm is done, side effects are hard to predict. A medical test is designed with the sole purpose of seeing the reaction in humans, for many this could be dangerous if the side effects
are severe. Plus, many subjects worry that even if the drug works, they are still not patients, they are subjects and the treatment could be discontinued or taken away, reducing the access to the treatment for the subjects (Getz & Borfitz 53).

At the heart of the debate is the understanding that human experimentation and testing is one of the most effective and groundbreaking means of scientific discovery. My interview with Harvard Medical Ethics professor Christine Mitchell enlightened me to understanding the power of medical testing. Without testing, there would be no advancement in medicine and human biology (personal communication, March 25, 2013). The scientific method is question, hypothesis, prediction, testing and analysis. She stated that without the steps of testing and analysis science cannot move forward in certain subjects (personal communication, March 25, 2013).

Additionally, universities like Harvard have dedicated ethics programs and ethics committees to ensure the safety of participants. Professor Mitchell spends half her time teaching a Medical Ethics course, and the other half working with families and patients with various ethical questions (personal communication, March 25, 2013). An example is helping the families and relatives of patients decide the best course of action when dealing with ethical dilemmas like life support (personal communication, March 25, 2013).

Professor Mitchell also told me that for every major medical project, especially public, there is always an ethics committee present (personal communication March 25, 2013). She is currently working on an ethics committee in charge of a project that is attempting to create a computer simulation of the human brain. Her job is discussing and debating various questions that will arise if certain medical discoveries are found. She assures me that there will most definitely be groundbreaking discoveries, but her role is to decide whether things like brain performance enhancing drugs and operations should be allowed for use (personal
A communication, March 25, 2013). Professor Mitchell is among many professionals who strive and work for safety and protection of test subjects.

In the book "Recreating Medicine" by Gregory Pence, he dedicates two chapters to the topic of re-creating bioethics. These chapters push forward thinking within the medical ethics community, however, there are some very good points he makes about the kinds of medical ethicists there are. Pence (2000) writes that there are two kinds of bioethicists. The first being the "outside" ethicist, who work outside of medicine and focus on global and larger scale questions (Pence, 184-85). They focus less on the individual cases within a hospital or care center, thus working outside of medicine. The second is the "inside" ethicist, who in contrast work inside medicine and deal with individual cases (Pence, 184-85). Inside ethicists like Professor Mitchell attempt to find the right answers to difficult clinical situations and dilemmas.

Pence (2000) argues that the split of two kinds of ethicists creates a problem. A problem that is found deep rooted in the functions of the two kinds of hospital ethics committees. Hospital ethics committees (HEC) are often created of people with a particular point of view, where they have an opinion that is supportive of an existing belief, and through that challenge a physician (Pence 192). The other HEC is one that contains an outside bioethicist, which is considered less credible, thus making it hard for the HEC to receive and cases (Pence 192). The issue then arises that if HEC's are supposed to cover "all the bases" in a sense and represent not only the opinion of inside ethicists (Pence 192). As Pence (2000) says, "there is a danger in only being an inside bioethicist. One can get too caught up with trying to understand and apply the norms inside medicine and rarely step back to criticize these norms" (185). HEC's require the insight of outside bioethicists because if not, then the problem of whether the HEC is helping physicians make decisions through the ethics of ordinary and common morality or is it creating an internal morality of medicine.
The Pharmaceutical Research and Manufacturers of America (PhRMA) is an organization that represents American pharmaceutical research and biotechnology companies. PhRMA (2012) states the medical testing on humans provides substantial benefits to society as well as the participants themselves. However, there are indeed risks involved, but guidelines ensure ethical treatment and the protection of subjects. The most important rights protected are the well being both physically and emotionally of patients as well as their consent. PhRMA supports the development of new therapies and drugs to improve the quality of life and treat disease (Pharmaceutical Research and Manufacturers of America [PhRMA] 23). PhRMA believes that clinical research is used to answer specific questions and sometimes these questions cannot be answered unless tested on humans (PhRMA 23). For example, benefits and risks to the greater population requires specific testing on participants. PhRMA (2012) states that the principles and guidelines of documents like the Nuremberg Code and the Declaration of Helsinki are standards for clinical testing.

PhRMA's article "Strict Guidelines Ensure Safe and Ethical Medical Testing on Humans" tries to show the reader the many steps they take to protect their participants. The many steps they take begin with the design of the clinical trial. Researchers try to balance the risk to participants with the benefits to the participant and the contribution to society (PhRMA 24). Second, their investigators and researchers are all highly qualified and professionally trained in specific and particular fields (PhRMA 24). Next sponsors are sure to train the investigator and researches on the treatment and procedure of the test (PhRMA 24). Lastly, informed consent without coercion from the participant is completely necessary (PhRMA 25). All participants are given adequate information about the benefits and risks of participating. Everything from the environment of the trials to the time it will take are all information the researchers must provide. Furthermore, all questions must be answered truthfully by the researches (PhRMA 27). If the participant is unable to provide their own consent, then the consent of a legal representative (parent or guardian) must be provided (PhRMA 27). Finally, the right to
withdraw and end a test or experiment is a right that the participant understands and knows (PhRMA 27).

PhRMA (2012) also states that their tests and experiments are closely monitored to further ensure the rights of participants are not violated. Firstly, any clinical trial or test must pass the an IRB's review. IRB's are Institutional Review Boards, which consist of many members on a committee that decide whether a clinical trial can or cannot be carried out. PhRMA (2012) ensures that before any trials begin, the procedure is reviewed by an IRB that has the ability to refuse any trial. IRB's have the power to force a change, disapprove and approve any and all trials. The IRB's are also provided any and all information on related studies and findings. Next, once the procedure and treatment is approved by the IRB and begun, careful monitoring is done by qualified professionals (PhRMA 27). All trials are monitored for their safe treatment of participants, good clinical practices and the accuracy of the data reported by the researchers (PhRMA 27). The monitors of a clinical trial have the power to end an experiment as well as remove a researcher. Finally, all information is shared with the Data and Safety Monitoring Board (PhRMA 27). A committee of people keep track of the data found and make sure it is valid, reliable and unbiased. PhRMA (2012) states, "Medical researchers recognize the importance of adhering to such standards because without a strong ethical framework study results would be reliable or respected".

PhRMA represents many of the pharmaceutical manufacturers in America. They are avid about protecting the rights of their subjects and participants. But, the thing to remember is that PhRMA represents profit organizations. Although the rules and guidelines they keep are very protective, it is key to remember that these medical tests and human experiments are not purely altruistic, or purely for the means of benefitting society. This seems obvious, however, when money is involved in anything, especially on the scale of multibillion dollar corporations there are more chances of corruption. What I mean is that there is a lingering variable in any
experiments or test, which is, how much profit will this product make. I think to understand human experimentation, we have to become comfortable with the idea of moderation, or everything in controlled amounts. Expecting a company to purely work outside of profit is improbable to say the least, and ineffective as well. Companies that do research require funding. It is important to keep in mind, that the saying, "money is the root of all evil" exists for a reason.

In an article titled, "Medical Testing on Humans Can Be Dangerous and Corrupt" by Paul Totso and Jeremy Olson essentially rebut the statement made by PhRMA and supporters of human experimentation. The article writes of the death of a schizophrenic subject named Dan Markingson, who killed himself participating in a trial on the treatment of antipsychotic drugs (Totso & Olson 33). The issues regarding this were that he was given a drug that was experimental rather than several drugs that had proven to work. Many people say that because the researchers withheld that information it was unethical (Totso & Olson 34). In addition, none of the researchers regarded the concerns presented by Markingson’s family (Totso & Olson 34). Also, following Markingson’s passing the test continued, even though it should have been stopped (Totso & Olson 34). Coupled with the fact that no government agency keeps track of the deaths or injuries during medical testing. The IRB in practice is also very open to loophole and mistakes because it is based upon self report.

Markingson’s unfortunate death occurred in 2004, and after analyzing the papers from the lawsuit, questions are raised about whether or not the researchers followed ethical guidelines (Totso & Olson 34). The IRB in place, which consisted of 57 experts, is also under questions as to the reasoning for not stopping the trials. In 2008, a judge ruled that the university and the IRB were immune from the lawsuit, meaning specific questions regarding Markingson’s death could not be answered (Totso & Olson 34). Leaving much speculation as to who’s responsibility it was that a subject died in a medical test.
Totso and Olson (2012) explain that the nature of an IRB is that it is based upon trust. The participants trust that the researchers will follow the guidelines, trust that if anything is wrong the researchers and the participants will speak up when even one of the guidelines is violated (35). The trust lies in the fact that even if the researchers risk financial and professional pressures, they will speak up. The power of an IRB is that it can shut down a test of study if the committee members feel that something is wrong. IRB's also have the power to implement and demand changes when necessary (Totso & Olson 35). Moira Keane (2012), the director of research at the University of Minnesota can only recall four studies that were stopped over a period of twenty years. In the case of Markingson's suicide, a critical guideline was broken because the researcher in charge of Markingson was his psychiatrist (Totso & Olson 34). If the doctor of a patient is conducting a study, for that doctor to recruit his own patient is unethical, however the IRB at the University of Minnesota did not stop the test (Totso & Olson 35).

Mary Beckman is a writer from Idaho who specializes in life sciences, her writings are often published in the Journal of National Cancer Institute. In her article titled, "Review Boards Are Inadequate to Ensure Ethical Medical Testing" she addresses issues that surround both the FDA and IRB's. In a federal study she cites, it is said that the FDA which is the US Food and Drug Administration does not have the ability to efficiently keep track of all the clinical studies that happen nationwide (Beckman 40). The FDA is understaffed for monitoring clinical trials and IRB's, and IRB's also function through trust, as mentioned by Totso and Olson (2012), thus the IRB relies on researchers to report any issues or ethical problems (34). This means at its very core, the IRB is not as ideal for protecting participants as it could be.

In the federal report, the inspector general for the US Department of Health and Human services highlighted the faults and flaws of the FDA. The inspector general reported that the FDA did not monitor clinical studies carefully enough, a statistic shows that the FDA monitors approximately 1% of the clinical studies that are performed (Beckman 40). The inspector
general wrote that the FDA has around 200 inspectors who have to monitor 350,000 researchers (Beckman 40).

The FDA rebuts by saying that changes are planned. After reviewing the report suggesting changes to monitoring trails, the FDA states that, "inspections are but one narrow part" because "in order to ensure the highest degree of human subject protection, [the] FDA carefully scrutinizes all protocols submitted to the agency and will require sponsors to revise protocols as necessary, thus ensuring the greatest protection of human subjects before a clinical investigation begins" (Beckman 41). The FDA believes that the report focuses too heavily on monitoring, and although that is important, making sure that trails and tests are ethical prior to beginning is equally important (Beckman 41). And to address the issue of monitoring, the FDA is modernizing its human subject protection protocols.

Even with the issues concerning the FDA, many scientists and researchers support the FDA. The problems with monitoring and under staff concerns are understood, but many believe that the FDA which is already in charge of a lot of things, is underfunded by the government (Beckman 41). The FDA lacks to money to hire more monitors, it is difficult to keep track of all the trials and tests that occur. Plus, many argue that the IRB's do a solid job at making sure guidelines and rules are followed (Beckman 41). And through the use of IRB's which are funded by the institution, relieves some of the financial stress on the FDA (Beckman 41).

However, there are issues with the structure of IRB's. IRB's are created to protect research participants, but not only is the IRB based on trust it is also, "based on paper, not on observing behavior" (Beckman 42). This means when a problem arises, the researcher reports to the IRB. The IRB does not police or observe the trial or test. The importance of the FDA in the grand scheme of things is that when private companies want a new treatment or drug approved, they get the FDA's approval. The FDA however, does not have the people or money to observe
the testing, what it does instead is make sure that the private IRB has approved of the drug (Beckman 42). This leaves a big loophole for unethical testing.

Understanding that the problem with IRBs is important because currently, IRBs are the system in place for protecting the participant. It seems to me, that the IRB is an idea that works fantastic on the drawing board. When the idea of an IRB was formulated, it must have seemed sufficient. But I believe that the system in place of protecting the wellbeing of people should be based on more than just trust. I think the problem with corrupt experiments is that the researchers abuse the trust they are given. Then it just seems to me the IRB does maybe half the job it is supposed to. The IRB must approve of all tests and variables that are going to be used, this seems like a great beginning. The next part would have to be inspections, and as of right now, inspections are not happening. Cases like Markingson, where the participant was harmed, highlight the missing piece of the IRB.

As decades pass, the days of Nazi prisoner experiments become more distant. People are much better protected and there are many safeguards in place for any one participating in an experiment. However, a population of people that is still heavily debated about is the prison population. In the US, around 743 adults of 100,000 are incarcerated, the highest in the world (Incarceration Statistics). As a result, the prison population is often struggling with human rights issues. Appendix C.

The Institute of Medicine published an article titled, "Medical Testing on Prisoners can be Done Ethically". The Institute of Medicine has the primary role of advising the government on the subjects of health and medicine (Institute of Medicine [IM] 51). In 2007, the US Department of Health and Human Services asked the Institute of Medicine to file a report on the ethical standards and guidelines for testing on the person population (IM 52). The Institute of Medicine (2012) highlights five primary points, that if strengthened would provide adequate protection for prisoners.
1. Define "prisoner" as a person whose freedom is restricted.
2. Universally apply all protection standards in a manner that is consistent
3. Approve research proposals based on their benefits and risks for participants
4. Require that, whenever possible, participants provide input on the design and execution of studies.
5. Strengthen all the regulations and agencies that govern the treatment of prisoners participating in the research studies. If medical testing is to be done on prison population it must follow ethical standards.

Using prisoners in medical experiments is extremely beneficial to both the researchers and the prisoners. Often times, just as it is the same for medical patients, access to a treatment or research improves the lives of those participating (IM 52). And the information gathered could be critical data and provide vital information for improving and furthering treatments. In this regard, one of the main goals is most certainly making sure that the benefits greatly outweigh the risks (IM 52). Although hard to define because benefit is a subjective word, the things that are trying to be avoided are the Nazi experiments. The publishing of the report showed that to improve the process, while keeping the five primary points in mind is to expand the definition of prisoner, where prisoner is not someone who has all their rights stripped. Next, ensure ethical protection. The ethical protection also has to be consistent and follows guidelines. Also, a focus on the benefit outweighs the risk structure. This will force all experiments to take into consideration of the prisoners. Furthermore, revise and edit the ethical guidelines that protect prisoner rights.

On the topic of prisoner experiments, it is difficult to say whether it should be allowed. There are many issues concerning the prison population in America, and prisoner experimentation is not on the top of the list. To be honest, I think it would be incredibly helpful and beneficial, but we would have to define the word "prisoner", as mentioned by the Institute of Medicine. Is a prisoner someone with less rights and freedoms as a citizen, or are they treated the same with the same concerns. Furthermore, when defining the word prisoner, it must be specified if anyone in prison is a prisoner, or are there varying terms and degrees of rights and
freedoms. An example is, whether a prisoner in a maximum security prison have the same benefits and rights to healthcare as a prisoner in minimum or federal prison. I believe that if I can think of some deep and inherent problems with prison testing, that testing on prisoners should not continue until every guideline and protection is accounted for. At least until the debate of human experimentations amongst everyone settled, then and only then should we focus on special populations.

Fighting to stop prisoner medical experimentation is a journalist named Silja J.A. Talvi. Talvi's article titled, "Medical Testing on Prisoners Is Unethical and Should Be Outlawed" speaks about the history of prisoner experimentation. It begins with the Nazi experiments during the holocaust, where Dr. Josef Mengele, also known as the Angel of Death, would test prisoners (Talvi 46). He focused primarily on women, and the things he did were horrendous. From there she talks about the dark history of medical experimentation based in the US. How experimenting on prisoners is not ethical under regulations of the Nuremberg Code. Yet medical experimentation on prisoners continues to happen. Although many reforms have been passed, the report in 2007 detailed all the short comings of prisoner experimentation (Talvi 47). The report was written as a solution for the flaws. Talvi (2012) argues that medical experimentation on prisoners should be stopped until the reforms have taken place. Until prison health care is consistent and up to standard. Talvi (2012) writes, "in light of this country's legacy of medically abusing captive populations- and to honor the Nuremberg Code- prison experimentation simply needs to come to an end.

My Senior Year Project was focused on sleep studies and the science of sleep deprivation. I set out to answer a question with my project and that question was, "what are the effects of sleep deprivation on mental, physical and social aspects of a person's life"? Through the process of designing, creating and performing the tests and experiment I became aware of something quite astonishing. I realized that corruption was an easy path to take and always close by. The
scientific process is "Question, Hypothesis, Prediction, Testing and Analysis", the step of creating a hypothesis is crucial, but I started to understand that as a researcher there are many things we expect to happen. I expected my logical and creative thinking to suffer, along with my muscular strength and endurance. My expectations were so clear that often times when reporting my data, I would be tempted to skew or alter my data. Corruption arises, because as soon as the researcher begins to take matters into his or her own hands, as soon as there is an alternate motive, whether it be to prove something with altered data or testing the effects of varied atmospheric pressure on the human body, as soon as the ultimate purpose of improving science and the standard of living for all people is forgotten, a path towards unethical and inhumane experiments is paved. The single most important quote I read said, "there will always be unethical scientists, at least as long as there are unethical people".

Human experimentation is one of the most interesting topics I have ever researched. It's such a unique case because in one hand it is an essential part of the scientific process. In other words, without human experimentation science, medicine and progress slows and often halts. But the dark history and the ease at which researchers corrupt experiments makes it extremely dangerous. With any debated issue there are always great arguments for both sides, and in the case of human experimentation this fact is doubly true. Human experimentation cannot be dismissed because of its accuracy and beneficial contributions, but it still must be challenged because as witnessed in the past, human experimentation is a wild beast to try and tame. However, the future is bright, and although those who argue against human experimentation find it hard to stop it altogether, at least they can rest easy knowing their work is helping to redefine and to reform experimentation.
References

-(B. Zhang, personal communication, April 21, 2013); An Associate Director at Shire HGT.

-(C. Mitchell, personal communication, March 25, 2013); A Harvard Medical Ethics Professor.


Appendix

A. Declaration of Helsinki.

A. INTRODUCTION
1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty.
3. The Declaration of Geneva of the World Medical Association binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act only in the patient’s interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.”
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.
B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH
10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
13. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.
14. The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in
this Declaration.
15. Medical research involving human subjects should be conducted only by scientifically
qualified persons and under the supervision of a clinically competent medical person.
The responsibility for the human subject must always rest with a medically qualified
person and never rest on the subject of the research, even though the subject has given
consent.
16. Every medical research project involving human subjects should be preceded by careful
assessment of predictable risks and burdens in comparison with foreseeable benefits to
the subject or to others. This does not preclude the participation of healthy volunteers in
medical research. The design of all studies should be publicly available.
17. Physicians should abstain from engaging in research projects involving human subjects
unless they are confident that the risks involved have been adequately assessed and can
be satisfactorily managed. Physicians should cease any investigation if the risks are
found to outweigh the potential benefits or if there is conclusive proof of positive and
beneficial results.
18. Medical research involving human subjects should only be conducted if the importance
of the objective outweighs the inherent risks and burdens to the subject. This is
especially important when the human subjects are healthy volunteers.
19. Medical research is only justified if there is a reasonable likelihood that the populations
in which the research is carried out stand to benefit from the results of the research.
20. The subjects must be volunteers and informed participants in the research project.
21. The right of research subjects to safeguard their integrity must always be respected.
Every precaution should be taken to respect the privacy of the subject, the
confidentiality of the patient’s information and to minimize the impact of the study on
the subject’s physical and mental integrity and on the personality of the subject.
22. In any research on human beings, each potential subject must be adequately informed of
the aims, methods, sources of funding, any possible conflicts of interest, institutional
affiliations of the researcher, the anticipated benefits and potential risks of the study and
the discomfort it may entail. The subject should be informed of the right to abstain from
participation in the study or to withdraw consent to participate at any time without
reprisal. After ensuring that the subject has understood the information, the physician
should then obtain the subject’s freely-given informed consent, preferably in writing. If
the consent cannot be obtained in writing, the non-written consent must be formally
documented and witnessed.
23. When obtaining informed consent for the research project the physician should be
particularly cautious if the subject is in a dependent relationship with the physician or
may consent under duress. In that case the informed consent should be obtained by a
well-informed physician who is not engaged in the investigation and who is completely
independent of this relationship.
24. For a research subject who is legally incompetent, physically or mentally incapable of
giving consent or is a legally incompetent minor, the investigator must obtain informed
consent from the legally authorized representative in accordance with applicable law.
These groups should not be included in research unless the research is necessary to
promote the health of the population represented and this research cannot instead be
performed on legally competent persons.
25. When a subject deemed legally incompetent, such as a minor child, is able to give
assent to decisions about participation in research, the investigator must obtain that
assent in addition to the consent of the legally authorized representative.
26. Research on individuals from whom it is not possible to obtain consent, including proxy
or advance consent, should be done only if the physical/mental condition that prevents
obtaining informed consent is a necessary characteristic of the research population. The
specific reasons for involving research subjects with a condition that renders them
unable to give informed consent should be stated in the experimental protocol for
consideration and approval of the review committee. The protocol should state that
consent to remain in the research should be obtained as soon as possible from the
individual or a legally authorized surrogate.
27. Both authors and publishers have ethical obligations. In publication of the results of
research, the investigators are obliged to preserve the accuracy of the results. Negative
as well as positive results should be published or otherwise publicly available. Sources
of funding, institutional affiliations and any possible conflicts of interest should be
declared in the publication. Reports of experimentation not in accordance with the
principles laid down in this Declaration should not be accepted for publication.
C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH
MEDICAL CARE
28. The physician may combine medical research with medical care, only to the extent that
the research is justified by its potential prophylactic, diagnostic or therapeutic value.
When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.

29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists. (See footnote*)

30. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

31. The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.

32. In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician’s judgment it offers hope of saving life, reestablishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

B. Link to my survey.

http://www.surveymonkey.com/MySurvey_Responses.aspx?sm=4jp%2f2%2fxY2HhAQhIg%2fxVe6DnutnDu1qe%2bvYHSiEFSUss%3d

United States is the World's Leading Jailer

Prisoners per 100,000 Population - 2008