Experiments on humans

Tomasz Ciesielski, Line-Kristin Larsen, Claudia Melis, Chia-Wei Vivian Wang
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1. Historical perspective

1.1. Background
Animal experimentations provide important, new and generally valid results, but certain findings required confirmation in man. Human experimentation is of particular relevance for clinical research. But, there were (and is until today) conflicts: on the one hand the goal of providing each patient with the best responsible treatment and doing no harm, and, on the other hand, the goal of gathering important information which is indispensable for the advancement of medicine and cannot otherwise be obtained. Human experimentation and research ethics evolved over time. There are numerous examples that involve abuse of humans through failure to disclose the purpose of the studies, failure to inform subjects of risks, coercion, undisclosed personal gain by researchers, unethical intentions of nations, and many other situations that are frequently cited as atrocities committed against humans. Much of the time, the subjects of human experimentation are prisoners, slaves, family members, or the experimenter himself.

1.2. To the middle of the 20th Century
In reviewing the history of human experimentation, an event sometimes referred to as the first recorded prospective trial, although not designed as a scientific experiment, is described in the Bible, in chapter 1 of the book of Daniel. Daniel’s people eat one kind of food and the king’s men eat another type. After 10 d, the appearance of the study participants was noted, and Daniel’s people ‘appeared fatter in flesh than did the king’s men.’ As a result of this ‘prospective nutrition trial,’ Daniel and his people were permitted to continue to eat their own food rather than be forced to eat the king’s food.

Since antiquity occasional human experiments have been performed out of curiosity or in order to learn about disease and therapy. Such experiments had been performed mostly in haphazard, non-systematic and often inconclusive way. Sometimes prisoners condemned to death had been used for this purpose, and subjected to grisly procedures.

Some of the researches performed self-experiments. Famous example of such research was study of Johann Jorg who swallowed 17 drugs in various doses to record their properties. In Edward Jenner experiments, he tested smallpox vaccines on his son and neighbourhood children.

At the end of 18th century it was realized that more systematic studies in man are required. A new methods where introduced at that time. Good example is a work of Pierre Charles Alexandre Louis in 1830. He conducted carefully planed study using patients that allowed to convince that blood-letting was not an effective therapy. That was in contrary to the orthodox teaching of the time.
However there is no doubt that in many countries, apart from responsible investigations, striking abuses of human experimentation have occurred long before the outrageous atrocities of the Nazis, and before the Nuremberg Trials. In one of the more spectacular early cases of controversial human experimentation, the renowned dermatologist Albert Neisser (1855-1916) of Breslau was alleged to have transmitted syphilis to eight subjects by injecting a cell-free serum that had been derived from syphilitic patients and was assumed to provide immunity from the disease. It results in decree of the Prussian Ministry of Education that was the first attempt worldwide by any official authority to introduce formal procedures for regulation human experimentation. In spite of few cases the legacy of human experimentations and the moral question regarding it remained unresolved after the First World War. Many experiments were carried out in a responsible way on volunteers, but there was also objectionable experimentation on prisoners and inmates of institutions for the mentally retarded or children. Many studied were carried out without asking for consent.

1.2.1. The Nazi era
The worst instances were the inhuman, cruel and perverse experiments carried out in Nazi concentration camps and in special installations established by the Japanese military in Manchuria after 1932.

From 1933 to 1945, Japanese doctors in China performed thousands of cruel experiments on Chinese, Russians, Mongolians, and Koreans and killed all of them. At Unit 731 alone, at least 3,000 people were tortured and murdered. These experiments and vivisections can be classified under the following four categories:

(1) vivisections for training newly employed army surgeons
(2) intentional infection of diseases
(3) trials of non standardized treatments
(4) learning tolerance of the human body

Among the reasons why these cruel experiments where possible, the absolute power of the professors over their disciples is proposed. It is very characteristic of the Japanese system and in contrast with the Nazi human experiments and the human radiation experiments done in the United States. The experiments were possible on the basis of the authoritarian character of Japanese (and probably East-Asian) ethics. It is believed that the Japanese and East-Asian values, such as respect for authority and harmony, in the Japanese medical profession not only enable to perform the massacre by human experimentation in China during the period of 1933-1945 but also prevented a public investigation after the war.

One of the most negative chapters in the history of human experimentation includes the experiments
done under auspices of the Nazi regime from 1933 until 1945. At the war's conclusion, 23 Nazi doctors and scientists were tried for the murder of concentration camp inmates who were used as research subjects. Of the 23 professionals tried at Nuremberg, 15 were convicted. Seven of them were condemned to death by hanging and eight received prison sentences from 10 years to life. Eight professionals were acquitted.

The Nazi experiments fell into three basic categories:

1. Medico-Military Research – freezing, high altitude, sea water, sulphanilamide and tuberculosis experiments
2. Miscellaneous, Ad Hoc Experiments – poison and wound experiments
3. Racially Motivated Experiments – artificial insemination, sterilization and twin experiments, as well as Jewish skeleton collection

The experiments were characterized by several shocking features. Persons were forced to become subjects in very dangerous studies against their will; nearly all subjects endured incredible suffering, mutilation, and indescribable pain; the experiments often were deliberately designed to terminate in a fatal outcome for their victims.

One of these young mass murderers was Josef Mengele M.D., Ph.D. He worked from 1938 to 1940 as a postdoc at the Institute of Genetics (Erbbiologie) and Race Hygiene at Frankfurt University under Otmar von Verschuer, researcher having excellent international reputation. On 31 May, at the age of 32, Mengele arrived in the concentration camp at Auschwitz as a camp doctor and began genetic ‘research’ on twins. Identical twins were ideal for these studies as they have identical genetic material and, therefore, the reactions of one twin to various stimuli or injections with lethal germs could be compared with that of the other. Although the aims of Mengele’s experiments — identifying the genetic basis for susceptibility to infectious disease — were intrinsically interesting, these were conducted without scientific method or rigor. Not only were his experiments unethical, but also they were scientifically meaningless. Over 1,000 twins were selected for these experiments — only 200 were alive when the camp was liberated in 1945. After the end of the war Mengele escaped to South America and probably died in 1979.

Another German ‘investigator’ was Dr. Hermann Voss. Interestingly Dr. Voss became quite well known after the war as a professor of anatomy at the University of Jena. During the war Dr. Voss carried out research on the blood content of the spleen by using specimens from the Gestapo guillotine in Posen, in occupied Poland. The Gestapo guillotine was very active against the Polish resistance and supplied Dr. Voss with countless spleens. The bodies were then cremated anonymously. Dr. Voss reflected on the crematorium in his diary: ‘Yesterday I looked at the furnace in the crematorium. Now it serves to incinerate executed Poles. Looking into such a furnace
makes me feel calm and comfortable. How nice it would be to chase the whole Polish population through such furnaces. Then the German people would finally get some rest’. Then he followed writing to professor Schoen and asked him to remember me when the chair for anatomy at the University becomes vacant.

After the trials of the criminals the ten basic principles known as the Nuremberg Code (1947) were established by Military Tribunal at Nuremberg. The main contents are:

1. The voluntary consent of the human subject is absolutely essential;
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature;
3. The experiment should be based on the result of animal experimentation and so designed that the anticipated results will justify its performance;
4. The experiment should be so deducted as to avoid all unnecessary physical and mental suffering and injury;
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur, except, perhaps, in those experiments where the experiments also serve as subjects;
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment
7. Proper preparation should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death;
8. The experiment should only be carried out by scientifically qualified persons;
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end;
10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, with the exercise of the good faith, superior skill, and careful judgment required of him, that continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

The Nuremberg Code marks the beginning of a new era in human experimentation. However the Nuremberg Code was did not address the question of proxy consent for experimentation with incompetent subject, and neglected a number of other ethical questions that are relevant for medical research involving human subjects.

1.3 From the middle of the 20th Century – until today

In spite of the several regulations regarding regulation of human experimentations that appeared
after Nuremberg trial, unethical experiments were conducted. Dr. Henry Beecher in his article (1966) cited 22 cases of human experimentation carried out largely at university centres in the United States in the years after World War II. These experiments included testicular irradiation, injection of live tumour cells into people, withholding of known effective therapies, and others. It is clear that these subjects had no clear idea of what was being done to them. Many were institutionalized because of retardation or incarcerated prisoners who lacked an opportunity not to participate. It has been asserted that some American physician saw the Nuremberg Code as applying to ‘them’ and no ‘us’ and ‘it was a good code for barbarians but an unnecessary code for ordinary physician’. The defining moment for a change in the attitudes toward human experimentation in the United States came when the scope of a non-therapeutic experiment of syphilis became a headline in a Washington, newspaper, so called Tuskegee syphilis study. Other ethical problems of the research on humans that have arisen in the past and are still discussed are studies on the efficacy and side effects on drugs or treatments – clinical trials. The term clinical trial has been used first time in print in 1931. Since the 1970s, the Food and Drug Administration (FDA) in the USA and similar authorities have stipulated so called randomized clinical trials, RCT (Phase I, II, II, IV study). For example controversy encountered with RCTs originated in 1990 – tests that could not have been conducted in industrialized countries were carried out in a number of developing countries. It includes study of transmission frequency of HIV/AIDS from mother to child that has been carried out in the South Africa. In the study the drug Zidovudine were administrated to mother and child to prevent infection of HIV/AIDS. Of the 16 studies 15 were placebo- controlled randomized clinical trials. The control group did receive placebo that has been regarded unethical because the women in the control group are deprived of treatment although and effective one exists in the form of Zidovudine. This results in a long discussion in the highly respected New England Journal of Medicine where some of the authors strongly object to the placebo-controlled studies in such cases. This difficult ethical problems of clinical research in developing countries are still discussed in various statements and official documents.

2. Laws and regulation

2.1 International situation

Experiments on humans have been existed since ancient history. But no laws or regulations were established to protect the subjects of human experimentation, because the subjects were usually prisoners, slaves, family members or the experimenter him/herself. After the World War II, the world society was appalled by the barbarism during the war and those experiments performed on
human beings. Therefore, at the General Assembly of the United Nation in 1948, the Universal Declaration of Human Rights was adopted and reclaimed. The declaration was not legally binding, but it urged member nations to promote a number of human, civil, economic and social rights, asserting these rights are part of the foundation of freedom, justice and peace in the world. This declaration was also the first international legal effort to limit the behaviour of states and press upon them duties to their citizens following the human right norms. The Universal Declaration of Human Rights was also recalled in every declaration, convention or guidelines on biomedical research, clinical research, biology and science technology, that were adopted by the world society later.

Here are other declarations and conventions that world society has adopted and proclaimed since 1948:

- **Declaration of Helsinki** developed by the World Medical Association, is a set of ethical principles for the medical community regarding human experimentations. It was originally adopted in June 1964 and has since been amended multiple times; the latest was in Tokyo in 2004. The declaration was the first significant effort made by the medical community to regulate itself. It considers the conduct of clinical research and makes the important distinction between therapeutic and nontherapeutic research. Some articles from the Declaration:

  - **Article 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.
  - **Article 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.
  - **Article 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. (...)

- **Vancouver convention**
  A group of editors of general medical journals established guidelines for the format of manuscripts to their journals. The group became known as the Vancouver Group, it expanded and evolved into the International Committee of Medical Journal Editors. The guidelines include ethical principles related to publication in biomedical journals. In Vancouver convention
they have an own section about the protection of human subjects and animals in research, which says ‘when reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration…’ and ‘if doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study.’

- UNESCO

Since 1970’s, UNESCO has been involved in the field of bioethics. They recognized it was a growing problem that needed the international community to state universal principles that will provide a foundation for humanity’s response to the increasing dilemmas and controversies that science and technology present. The UNESCO Bioethics Program was created in 1993, on the basis of the concern of the progress in the life sciences like stem cell research, genetic testing and cloning, which gives human beings new power to improve our health and control the development process of all living species. Three Declarations on the bioethics and human rights were adopted by UNESCO since 1997, and they are:

1. **Universal Declaration on the Human genomes and Human Right, adopted in 1997**

   This declaration is an international instrument for the protection of the human genome. In the preamble of the declaration says that recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics.

2. **Universal Declaration on Human Genetic Data, adopted in 2003**

   The Declaration established a standard-setting instrument, laying down the ethical principles that should govern their collection, processing, storage and use of human genetic data.

3. **Universal Declaration on Bioethics and Human Rights, adopted in 2005**

   Background of this declaration was a growing number of scientific practices have extended beyond national borders and the necessity of setting universal ethical guidelines covering all issue raised in the field of bioethics. The aim is to establish an international standard-setting that
can help states making laws on the dilemmas that caused by the rapid developments in science and technology.

Some examples from articles of the Declaration:

In Article 3 – *Human dignity and human rights* says that human dignity, human rights and fundamental freedoms are to be fully respected. The interests and welfare of the individual should have priority over the sole interest of science or society.

The Article 5 – *Autonomy and individual responsibility* is about autonomy of persons to make decisions, and for persons who are not capable to make their decisions, special measures must be taken to protect their rights and interests.

- **WHO’s Operational Guidelines for Ethics Committees**
  The guidelines are to contribute to the development of quality and consistency in the ethical review of biomedical research. The purpose of an Ethic Committee is to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants. It also says that the committees need to have independence from political, institutional, professional and market influences.

- **Council of Europe – Convention on Human rights and Biomedicine, adopted in 1997**
  This is the first legally-binding international text designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances. The interests of human beings must always come before the interests of science or society. It bans all forms of discrimination based on the grounds of a person’s genetic make-up and allows the carrying out the predictive genetic tests only for medical purposes. It allows genetic engineering only for preventive, diagnostic or therapeutic reasons and only where it does not aim to change the genetic make-up of a person’s descendants. The convention sets out rules related to medical research by including detailed and precise conditions, especially for people who can not give their consent. The additional protocols contain more detailed examination of the subject of ethical review and ethics committees.

**2.2 Norwegian situation**

Norway follows the international guidelines according to making laws and regulations on bioethical research. In additional to those international declarations and conventions that were mentioned earlier, we have several laws and regulations that are very strict on the treatment of biological materials, research participants and private data. And the aim of these laws and regulations is to
protect research participant’s fundamental rights and ensure that the goal of the research will not override the health, well-being and care of the research subjects.

All the ethical research questions are treated by three national research ethic committees and five regional committees for medial research ethic. Both national and regional committees are independent consultative bodies and they cooperate across borders, with committees of other Scandinavian countries, the European Group on Ethics in Science and New Technologies, Council of Europe and UNESCO. The committee is appointed by Utdannings- og forskningsdepartemanetet, and they need to be independent from political, institutional, professional and market influences.

Here are some laws that are important for research performed on humans:

1. Genteknologiloven: entered into force on April 2nd 1993. To ensure that the production and the use of gene modified organisms occur in an ethical and social defensible way.
2. Personopplysningsloven: entered into force on January 1st 2001. It regulates electronically treatment of personal information. The aim is to prohibit personal data not be infringed during the research.
3. Helseregisterloven: the same purpose as Personopplysningsloven. Entered into force on May 18th 2001. The law gives the health service and administration the right to get the personal data without infringes personal security.
4. Bioteknologiloven: entered into force on December 3rd 2003. To ensure that the medical use of biotechnology does not violate the principles of human dignity, respect and rights.
5. Biobankloven: entered into force on February 21st 2003. To ensure that collection, storage, treatment and destruction of biological materials is performed in an ethical defensible way.
6. Lov om behandling av etikk og redelighet i forskning is the latest law about the treatment of ethics and integrity in research. It is published in 2006 and will entry into force on July 1st 2007.

3. Pharmacological testing

3.1 Human test subjects

Medical research on humans can give answers to how drugs or treatments work on humans. Animals are commonly used as test subjects in medical experiments but the effect observed in animal studies might differ from the results obtained with human subjects. As medical experiments are often hazardous regarding to human health few people will willingly enter a study that can cause trauma or death for the cause of the greater good. That has lead to some
controversial experiments where the scientist lose track of the test subjects as human beings and harm them in the name of science.

Some experiments have solved this problem by deceiving the people attending the study and further using test groups which have few other options.

Humans belonging to weak groups in the society seem to be the individuals susceptible to end up in studies using human beings. The reason for this is the unwillingness among most people to volunteer for potentially damaging studies in the name of human benefit. Individuals that actually sign up are thus often people with no or few other alternatives to get an income.

The studies are often paying a large sum of money to the subjects of the study. An increasing problem for medical studies using humans is disloyal test subjects. Meaning that many participants attend more than one study at the same time, in order to increase the income gained from the trials. The consequences of this are likely to be damaging both for the test subject and for the study. Individuals attending different studies testing the effect of drugs for instance can get severe side-effects by mixing drugs and the mix may also alter the reaction that the study is aiming to find.

3.2 The Tuskegee Study

The Tuskegee Syphilis Study ran from 1932 until the 1970’s and was started by Taliaferro Clark. This study became known due to its ruthless handling of the humans involved in the study. It started out as a study on the incidence of syphilis in a population of black men in Macon County, Alabama.

The plan was to study the subject for 6-8 months and then treat him with the medicine which was available at the time. The intention was to find a better treatment in order to benefit the health in the local community. By studying the natural history of the disease the results could be used for a greater good.

In order to get people to participate the truth was effectively concealed from the subjects attending the study. They were told that they had ‘bad blood’ and the true diagnosis was not revealed. The patients were further offered a free warm meal on test days, a free bus ride to the study site, and a paid funeral in case of death as payment. In total 400 syphilitic men and 200 healthy men attended the study. During the early days of the study the scientists leading it did not know of any cure for syphilis and the study had not passively killed any of its test subjects yet.

By 1947 penicillin was a common treatment for syphilis. However, the scientists in the Tuskegee study deprived subjects of the study this treatment in order to continue the study of how syphilis developed in the patient. They maintained control groups that were prohibited from receiving any medicine. These control groups were deceived into believing that they revived proper medicine but...
in reality they were given a placebo treatment. This led not only to the subjects’ deterioration in health but also to the continued spread of the disease in the community. Participants were also prohibited from attending any other syphilis treatment programs in the area thus staying under the scientist’s control.

A further assault towards the participants was the idea to extract spinal taps from the infected individuals to check for signs of neurosyphilis. In order to get the participants cooperation they told the study subjects who signed up for spinal taps that it was a ‘special treatment’ that was free of charge.

The Tuskegee study was not a secret study. It was known in the scientific world. Several papers were published, the first one in 1954.

3.3 Aftermath

In 1966 Peter Buxton expressed his concern about the moral of the study and sent a complaint to the Division of Venereal Diseases where he explained about the horrific conditions experienced by the subjects of the study. The complaint was rejected with the reasoning that it was important to complete the study and wait for the last test subjects to die and get autopsied. Fortunately, he did not settle with this and went to the press with the truth about the Tuskegee study. The article was first released in the Washington Star the 25th of July 1972.

The severity and extreme length of the Tuskegee study appalled US citizens and was among the most influential in shaping public perceptions about research involving humans. The study has further done great harm to medicine, invoking distrust, especially among African Americans, to medical research.

3. 4 The Body Shop: testing cosmetics on humans

The UK and the Netherlands are currently the only countries in the world to have introduced a full ban on the testing of cosmetics on animals. The Body Shop believes cosmetics’ testing on animals is unethical, unnecessary and should be banned.

They do not test their products or ingredients on animals nor do they commission others to do so. To ensure the safety of their products they use alternative ‘non-animal’ tests such as microbiological analysis using computer modelling and controlled testing on carefully monitored groups of human volunteers.
4. Genetic and human embryonic stem cell research

The main feature of genetic research is that it will not only influence the people checked but the whole lineage both in the past and in the future.

A persistent question is whether the providers of the genetic material have any rights on the products created with it. Most consent forms exclude property rights from the subjects.

Human embryonic stem cell research could have great potential to cure disorders in which cellular degeneration is known to occur. These include for example Type 1 diabetes mellitus, Parkinson’s disease, cancer and spinal injuries. Nevertheless, some people believe that pre-implantation embryos are potential human beings and therefore this type of research is immoral.

4.1 Methods

The objective is to have stem cell lines derived from embryonic stem cells. Cells from these lines are ‘totipotential’ because they could be transformed into any kind of tissue by means of the proper biological and chemical manipulations. Embryonic stem cell lines can be created by three ways:

1) Eggs and sperm can be obtained from donors, mixed in a Petri dish and the egg fertilized for the purpose of producing a stem cell line for research.

2) Annually, many thousands of infertile couples create embryos for in-vitro fertilization (IVF), by having their eggs and sperm mixed and fertilized in a Petri dish. The best embryos are incubated long enough to become blastocysts (4 to 5 days old in humans, consisting of 50-150 cells). Usually three are implanted into the potential mother’s uterus. The remaining embryos are stored in liquid nitrogen in case of pregnancy failure or for later use if the family wants another child. Many of them eventually become available for research. With informed donor consent from both parents, these frozen embryos have the potential for providing most of the necessary raw material for stem cell research.

3) Somatic cell nuclear transfer: young women donate ova by undergoing the ‘superovulation’ process, as do infertile women. The egg has its nucleus containing the genetic material removed. The nucleus of an adult cell of research interest is placed into the enucleated egg.

This process has the advantage that theoretically stem cells could be produced with any genetic condition of interest by introducing the nucleus from a person with that condition. The major disadvantage is that a supply of human unfertilized eggs is required to do the research. Until a reliable source of human ova can be obtained without either a large payoff or by coercion, this process is unlikely to become the main source of embryonic stem cells. However, it is plausible that
mothers of individuals with a serious disorder such as Type 1 diabetes mellitus would be willing to donate eggs to further research progress.

4.2 Ethical issues and present status
The core issue related to human embryonic stem cell research is the status of the early embryo, whether it is a human being that must be protected or is it a collection of cells that will not become part of humanity until further development.

On August 23, 2006, the online edition of Nature scientific journal published a letter by Dr. Robert Lanza (medical director of Advanced Cell Technology in Worcester, MA) stating that his team had found a way to extract embryonic stem cells without destroying the actual embryo. This technical achievement would potentially enable scientists to work with new lines of embryonic stem cells derived using public funding. More recently, this paper has come under some criticism since its examination reveals that the described process is highly inefficient, and in addition, no embryos survived the manipulation.

5. Behavioural research on humans
Most experiments designed to study sociology or human behaviour requires data collection from human subjects. This data can be collected either through observation studies or questioning the subjects directly. An observation study is one where the researcher simply ‘observes’ the subjects, and has little or no interaction with them. It is a most effective way of studying young children who are unable to respond to questions, it is regarded as more convenient and less intrusive for the subject and supposed to capture an individual's genuine reaction. Drawbacks of this method are that it is limited to collecting data about visible characteristics or behaviour and it is more time consuming to reach a sufficient high sample size to draw valid (statistically supported) conclusions. The questioning method of data collection involves direct interaction between the researcher and the subjects, through the use of interviews or surveys. Questioning is a valuable method for collecting information on unobservable variables such as feelings, motives, perceptions, attitudes, etc. The advantages are that it is a less time consuming method for capturing sufficient data, while drawbacks of this method are that the questions, or the mere fact of being questioned, may influence a subject's responses.

Nowadays information on human behaviour is collected by assuring anonymity and by limiting the psychological consequences to participants. Several behavioural experiments that have been
conducted on volunteers at the beginning of human behavioural science, would nowadays be ethically questioned both for the psychological consequences they might have on participants and for their uncertain scientific value.

5.1 The Milgram experiment

‘Good experiments, like good drama, embody verities.’ (Stanley Milgram, 1973)

‘It may be that we are puppets-puppets controlled by the strings of society. But at least we are puppets with perception, with awareness. And perhaps our awareness is the first step to our liberation.’ (Stanley Milgram, 1974)

The Milgram experiment is one of the historically famous scientific experiments on human behaviour. It was first described by Stanley Milgram, a researcher in human psychology at Yale University, in an article entitled ‘Behavioral study of obedience’, published in the Journal of Abnormal and Social Psychology (1963). The aim of the experiment was to measure the willingness of a person to obey an authority in doing something that may conflict with is own conscience. One of the reasons behind this test was that many war criminals after the Second World War, who were responsible for example of atrocities during the Holocaust, defended themselves by claiming that they were ‘just following orders’. Could this really happen in the real world, that an adult person would easily go against is own perception of right and wrong because obeying an authority?

5.1.1 Methods

Volunteers for the experiment were recruited through newspaper and direct mail, they were paid an equivalent of about 30 current dollars. The participants were males between 20 and 50 years-old, from all educational backgrounds, ranging from elementary school to doctoral degree. They were told that they would be participating in an experiment to test the effects of punishment on learning. A piece of paper was then given to the participant and another to an actor that was pretending to be also a paid volunteer. The participant was led to believe that one of the tickets said ‘learner’ and the other said ‘teacher’, and that they were assigned randomly. In fact, both slips said ‘teacher’, thus guaranteeing that the participant was always the ‘teacher’. At this point, the ‘teacher’ and ‘learner’ were separated into different rooms where they could communicate but not see each other. The ‘teacher’ was given a 45-volt electric shock from the electro-shock generator as a sample of the shock that the ‘learner’ would apparently receive during the experiment. The ‘teacher’ was then given a list of word pairs which he was to teach the learner. The teacher began by reading the list of word pairs to the learner. The teacher would then read the first word of each pair and read 4
possible answers. The learner would press a button to indicate his response. If the answer was incorrect, the learner would receive a shock, with the voltage increasing with each wrong answer. If correct, the teacher would read the next word pair.

In reality, there were no shocks, but only a tape recorder synchronized with the electro-shock generator, which played pre-recorded sounds for each shock level. When the voltage increased to a certain level, the actor started to bang on the wall that separated him from the subject. After several times banging on the wall and complaining about his heart condition, the learner gave no further responses to questions and no further complaints. At this point, many people indicated their desire to stop the experiment and check on the learner. Some test subjects paused at 135 volts and began to question the purpose of the experiment. Most continued after being assured that they would not be held responsible. A few subjects began to laugh nervously or exhibit other signs of extreme stress once they heard the screams of pain coming from the learner.

When subject indicated his desire to stop the experiment, he was told in succession:

1. Please continue.
2. The experiment requires you to continue, please go on.
3. It is essential that you continue.
4. You have no choice, you must continue.

If the subject still wished to stop after all four successive phrases, the experiment was brought to an end. Otherwise, it was stopped after the subject had given the maximum 450-volt shock three times in succession.

5.1.2 Results

Before the experiment was conducted Milgram asked fellow psychologists what they thought the results would be. They unanimously believed that not more than 0.1 percent of the people tested would give the maximum voltage.

In reality 67.5 percent (sample size = 40) of experimental participants administered the 450-volt shock, though many appeared uncomfortable in doing so. No participant refused to give further shocks before the 300-volt level.

5.1.3 Criticisms

The experiment raised questions about the ethics of scientific experimentation itself because of the extreme emotional stress suffered by the participants (even though it could be said that this stress was brought on by their own free actions). Most modern scientists would consider the experiment unethical today, though it resulted in valuable insights into human psychology.
84 percent of the participants surveyed later said they were ‘glad’ or ‘very glad’ to have participated. Many later wrote expressing thanks. Six years later (during the Vietnam War), one of the participants in the experiment sent correspondence to Milgram, explaining why he was ‘glad’ to have been involved despite the apparent levels of stress, because he understood how easily one can submit to an authority and he said that he was fully prepared to go to jail if he was not granted conscientious objection status.

5.2 Stanford prison experiment

‘It was ethical because it followed the guidelines of the Stanford human subjects ethics committee that approved it. There was no deception; all subjects were told in advance that if prisoners, many of their usual rights would be suspended and they would have only minimally adequate diet and health care during the study. But it was unethical because people suffered and others were allowed to inflict pain and humiliation on their fellows over an extended period of time.’ (Zimbardo, 1996)

The Stanford prison experiment is a psychological study on human response to captivity and prison life and the effects of imposed social roles on behaviour. It was conducted in 1971 by a team of researchers led by Philip Zimbardo of Stanford University. Volunteers played the roles of guards and prisoners and lived in a fake prison. However, the experiment quickly degenerated and was ended earlier than planned.

Aim of the experiment was to test the hypothesis that prison guards and convicts were self-selecting, of a certain disposition that would naturally lead to poor conditions in that situation.

5.2.1 Methods

Participants were recruited via a newspaper advertisements and offered and equivalent of today’s 80 dollars to participate in a two-week ‘prison simulation’. 24 participants were selected according to psychological stability and health. These participants were predominantly white, middle-class young males. All were college undergraduates.

The group of twenty-four young men was divided in half at random into an equal group of ‘prisoners’ and ‘guards’. Although prisoners later said they thought the guards had been chosen for their larger physical size, there was no objective difference in stature between the two groups.

The prison itself was run out of the basement of the Stanford Psychology Department. A number of rules were set up in order to promote disorientation and depersonalization: no clocks,
no view of the outside world were allowed, guards were given wooden batons and a khaki, military-style uniforms they had chosen themselves at a local military surplus store. They were also given mirrored sunglasses to avoid eye contact. Prisoners were to wear only ill-fitting muslin smocks (without underwear) and rubber thong sandals. They were referred to by assigned numbers instead of by name. These numbers were sewn onto their uniforms, and the prisoners were required to wear tight-fitting nylon pantyhose caps to simulate shaven heads similar to those of military basic training. In addition, they wore a small chain around their ankles as a constant reminder of their captivity and oppression.

The day before the experiment, guards attended a brief orientation meeting, but were given no formal guidelines, other than that no physical violence was permitted. They were told it was their responsibility to run the prison, which they could do in any way they wished.

The participants who had been chosen to play the part of prisoners were told simply to wait in their homes to be called on the day the experiment began. Without any other warning, they were ‘charged’ with armed robbery and arrested by the actual Palo Alto police department, who cooperated in this part of the experiment.

The prisoners were put through a full booking procedure by the police, including fingerprinting and having their mug shots taken, and were informed of their Miranda rights. They were transported to the fake prison where they were strip-searched, disinfested and given new identities.

5.2.2 Results

The experiment very quickly degenerated. Prisoners suffered and accepted sadistic and humiliating treatment from the guards, and many of them showed severe emotional disturbance.

The prison quickly became unhealthy and inhospitable. The use of the bathrooms became a privilege which often was denied. Some prisoners were made to clean toilets using their bare hands.

‘Bad’ prisoners were forced to sleep on the floor without clothing. Food was also frequently denied as a means of punishment. Prisoners endured forced nudity and even homosexual acts of humiliation.

As the experiment proceeded, several of the guards became progressively more sadistic, especially at night, when they thought the cameras were off. Approximately one-third of the guards exhibited authentic sadistic tendencies. Most of the guards were upset when the experiment was cut off earlier than expected. Uncontrollable crying and disorganized thinking were common among the prisoners.

Two of the prisoners suffered such severe trauma that they were removed from the experiment early and replaced. After only six days of the planned two weeks, the experiment was shut down.
5.2.3 Criticisms

The experiment was widely criticized as being unethical and bordering on unscientific. Because it was a field experiment, it was impossible to keep scientific controls. Conclusions and observations drawn by the experimenters were largely subjective and anecdotal, and the experiment would be difficult for other researchers to reproduce.

Some of the experiment's critics argued participants were purely engaging in role-playing. The experiment was also criticized on a basis of ecological validity. Many of the conditions imposed in the experiment were arbitrary and may not have correlated with actual prison conditions. Finally, the sample size was very small, with only 24 participants taking place for a short period of time. And given that all 24 were interacting in a single group, the true sample size might be regarded as 1.
6. References (ordered by topic)

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15. Teaching the responsible conduct of research utilizing a case study approach http://www.medsch.ucla.edu/public/korenman/