

Human Experimentation Ethics

Troy Anderson, Emily O'Brian, & Elizabeth Pearson

Conversation Starters:

1. Should Phase 1 trial drugs be tested on humans? Why or why not? What are some of the ethical implications?
2. Should unnecessary clinical trials be permitted? For example, trials testing “copy drugs” or cosmetic improvements such as growth hormones?
3. Do you agree with the patient-centered paradigm placing patients as “full partners throughout the clinical trial process, and not only as volunteer research participants”? (537)
4. Do you find medical research and medical care to be in conflict? When are sham surgeries worth it to achieve double-blind, placebo-controlled trials? (538)
5. Do patients with life-threatening conditions (and no comparable or satisfactory alternative therapy) have a “right to try” an investigational New Drug (IND)?
6. Why would you participate in a clinical trial?
7. Should clinical trials be conducted on children or those with mental disabilities? Why or why not?
8. There is a memory drug being tested at VUMC. They are looking for human subjects to test its effectiveness. The advertisement says that participants will be compensated with \$3,000 for being admitted to the hospital for 24 hours for observation of the drug's effects. However, due to the continuous testing of the drug, there are possible side effects of memory loss. Would you participate in this study? Is it ethical to advertise this to students at the university? Why or why not?

Case Studies:

Discuss when experiments in the pursuit of “medical/scientific understanding” cross a line. These studies are clearly amoral, but consider how they might be applied to future human experimentation.

1. Tuskegee Study on Syphilis

In 1932, the Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. The study involved 600 black men – 399 with syphilis, 201 who did not have the disease. It was **conducted without the benefit of patients’ informed consent**. Researchers told the men they were being treated for “bad blood,” a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. **Although originally projected to last 6 months, the study actually went on for 40 years.**

In July 1972, public outcry led to review of the study. A panel found that **the men had agreed freely to be examined and treated. However, there was no evidence that researchers had informed them of the study or its real purpose.**

...Even when penicillin became the drug of choice for syphilis in 1947, **researchers did not offer it to the subjects**. The subjects were ever given the choice of quitting the study, even when this new, highly effective treatment became widely used.”

--Modified from Center for Disease Control

2. Unit 731

“From 1937 to 1945, the imperial Japanese Army developed a covert biological and chemical warfare research experiment called Unit 731. Based in the large city of Harbin, Unit 731 was responsible for some of the most atrocious war crimes in history. Chinese and Russian subjects — men, women, children, infants, the elderly, and pregnant women — were subjected to experiments which included the removal of organs from a live body, amputation for the study of blood loss, germ warfare attacks, and weapons testing. Some prisoners even had their stomachs surgically removed and their esophagus reattached to the intestines.”

-- Best PsychologyDegrees.com

3. Radioactive Materials in Pregnant Women

“Shortly after World War II, with the impending Cold War forefront on the minds of Americans, many medical researchers were preoccupied with the idea of radioactivity and chemical warfare. In an experiment at **Vanderbilt University**, 829 pregnant women were given “vitamin drinks” they were told would improve the health of their unborn babies. Instead, the drinks contained radioactive iron and the researchers were studying how quickly the radioisotope crossed into the placenta. At least seven of the babies later died from cancers and leukemia, and the women themselves experienced rashes, bruises, anemia, loss of hair and tooth, and cancer.”

-- BestPsychologyDegrees.com

4. Stanford Prison Experiment

“Conducted at Stanford University from August 14-20, 1971, the Stanford Prison Experiment was an investigation into the causes of conflict between military guards and prisoners. Twenty-four male students were chosen and randomly assigned roles of prisoners and guards. They were then situated in a specially-designed mock prison in the basement of the Stanford psychology building. Those subjects assigned to be guards enforced authoritarian measures and subjected the prisoners to psychological torture. Surprisingly, many of the prisoners accepted the abuses. Though the experiment exceeded the expectations of all of the researchers, it was abruptly ended after only six days.”

-- BestPsychologyDegrees.com