

Nuremberg Code Establishes The Principle Of Informed Consent



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Legal document

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Source: Excerpt of the verdict in the case of *U.S.A. v. Karl Brandt et al.* ("Doctors Trial"), contained in *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10* (Washington, D.C., U.S. Government Printing Office, 1949), vol. 2, pp. 181-183.

About the Author: After [World War II \(/history/modern-europe/wars-and-battles/world-war-ii\)](#) (1939–1945), the Allied nations established a series of International Military Tribunals, mostly at Nuremberg, Germany, to try several high-ranking Nazis as war criminals. These trials sought to bring to justice those responsible for the atrocities of the Holocaust. Among the defendants were physicians who had either ordered or performed the torture or murder of prisoners in numerous Nazi concentration and death camps.

INTRODUCTION

Since ancient times, beneficence has been a key principle of the medical profession, enshrined in the [Hippocratic Oath \(/medicine/anatomy-and-physiology/anatomy-and-physiology/hippocratic-oath\)](#) and subsequent codes of medical ethics. Beneficence entails that physicians must always put the needs and welfare of patients first. By extension, bioscientists must always put the needs and welfare of human research subjects first. However, until the verdict was

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handed down in the Nuremberg "Doctor's Trial," the specific rights of human subjects of modern biomedical research were not codified.

Twenty-three physicians, including Karl Brandt, [Adolf Hitler \(/people/history/german-history-biographies/adolf-hitler\)](#)'s personal physician, were charged as defendants at Nuremberg. The most notorious offender, [Josef Mengele \(/people/history/german-history-biographies/josef-mengele\)](#) of Auschwitz, escaped and was never brought to trial. The court found that the Nazi government had instituted a clear policy of performing cruel and unnecessarily painful experiments of dubious scientific merit on non-consenting prisoners, mostly Poles, Jews, Gypsies, homosexuals, and the handicapped. The trial, under judges Walter B. Beals, Harold L. Sebring, Johnson T. Crawford, and Victor T. Swearingen, all Americans, lasted from December 9, 1946, to August 20, 1947. Seven defendants were acquitted, sixteen were convicted; seven, including Brandt, were sentenced to be hanged.

One of the most important outcomes of the Doctor's Trial was the portion of the verdict subtitled "Permissible Medical Experiments," which defined the concept of [informed consent \(/medicine/divisions-diagnostics-and-procedures/medicine/informed-consent\)](#) and marked the beginning of international jurisprudence and regulation in this aspect of biomedical research ethics. Its ten enumerated principles became known as the "Nuremberg Code." Informed consent is what allows human research subjects to be active and voluntary participants rather than victims or unwilling tools of the scientific process.

PRIMARY SOURCE

PERMISSIBLE MEDICAL EXPERIMENTS

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

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1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

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 so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted 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 experimental physicians 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.

NEARBY TERMS

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7. Proper preparations 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 be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probably cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Of the ten principles which have been enumerated our judicial concern, of course, is with those requirements which are purely legal in nature—or which at least are so clearly related to matters legal that they assist us in determining criminal culpability and punishment. To go beyond that point would lead us into a field that would be beyond our sphere of competence. However, the point need not be labored. We find from the evidence that in the medical experiments which have been proved, these ten principles were much more frequently honored in their breach than in their observance. Many of the [concentration camp \(/social-sciences-and-law/law/crime-and-law-enforcement/concentration-camp\)](#) inmates who were the victims of these atrocities were citizens of countries other than the German Reich. They were non-German nationals, including Jews and "asocial persons," both [prisoners of war \(/social-sciences-and-law/law/international-law/prisoners-war\)](#) and civilians, who had been imprisoned and forced to submit to these tortures and barbarities without so much as a semblance of trial. In every single instance appearing in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers. In no case was the

experimental subject at liberty of his own free choice to withdraw from any experiment. In many cases experiments were performed by unqualified persons; were conducted at random for no adequate scientific reason, and under revolting physical conditions. All of the experiments were conducted with unnecessary suffering and injury and but very little, if any, precautions were taken to protect or safeguard the human subjects from the possibilities of injury, disability, or death. In every one of the experiments the subjects experienced extreme pain or torture, and in most of them they suffered permanent injury, mutilation, or death, either as a direct result of the experiments or because of lack of adequate follow-up care.

Obviously all of these experiments involving brutalities, tortures, disabling injury, and death were performed in complete disregard of international conventions, the laws and customs of war, the general principles of [criminal law \(/social-sciences-and-law/law/law-divisions-and-codes/criminal-law\)](#) as derived from the criminal laws of all civilized nations, and Control Council Law No. 10. Manifestly human experiments under such conditions are contrary to "the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience."

Whether any of the defendants in the dock are guilty of these atrocities is, of course, another question.

SIGNIFICANCE

For two decades after the Nazi atrocities came to light, a false and self-satisfied optimism pervaded the Western world that such cruel mockeries of good science could only happen under dictatorships such as Hitler's. While indeed the Nazi abuses of human research subjects were the worst, other blatant and unjustifiable violations of the principle of [informed consent \(/medicine/divisions-diagnostics-and-procedures/medicine/informed-consent\)](#), continued to occur throughout the West. Two examples are the study of syphilis among African-American men in Tuskegee, Alabama, funded by the [federal government \(/social-sciences-and-law/political-science-and-government/political-science-terms-and-concepts-28\)](#) from 1932–1972, and the study of hepatitis among children at the Willowbrook State School for the Retarded, Staten Island, funded by

[New York \(/places/united-states-and-canada/us-political-geography/new-york\)](#) State from 1955–1972.

As these abuses were gradually exposed, various governmental and professional agencies, both national and international, moved to counteract them and to prevent future occurrences. The Helsinki Declaration of the World Medical Association in 1964, the U.S. National Research Act in 1974, the Belmont Report of the U.S. Department of Health, Education, and Welfare in 1979, and the Common Rule of the U.S. Department of Health and Human Services in 1991 can all be seen as corollaries to the Nuremberg Code.

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