

The Nuremberg Code

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.
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 seemed 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 probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

"Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.]

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Nuremberg code turns 60

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This month marks sixty years since the Nuremberg code¹ – the basic text of modern medical ethics – was issued. The principles in this code were articulated in the context of the Nuremberg trials in 1947. We would like to use this anniversary to examine its ability to address the ethical challenges of our time. One of these is the question of scientific misconduct downstream to medical research, particularly when biased interpretations of clinical studies lead to an overoptimistic assessment of a new drug, which ends up being withdrawn from the market after harming many individuals, as happened with rofecoxib.² A second development is one that the Nuremberg judges could hardly have foreseen. In the age of AIDS, human research ethics began to be invoked not only to offer protection *from* research, but also to gain access *to* it. The AIDS crisis turned the fact of becoming a research subject into a kind of privilege, as it carried the hope of early access to treatment. Ethics must now reconcile two antagonistic objectives: protecting research subjects from possible harm, while ensuring non-discriminatory access to research for potential subjects; a tough balancing act.

The Nuremberg code evokes a dark time for medicine, yet remains a powerful symbol in inspiring the medical profession to stand up for its Hippocratic values and protect individuals from harmful medical experiments.

For the past 60 years, a series of ethical texts and instruments have relayed the Nuremberg court's opinion,³ and completed or interpreted the code in the multifaceted context of medical experimentation. The medical profession thus draws on a vast body of ethical reflection to ensure that scientific

advances do not prevail over the health and safety of individuals without their fully informed consent in medical experiments. However, we ask whether modern ethics and its binding instruments can always secure full protection to experimental subjects and beyond them, to the recipients of health care. In a context of relentless competition for resources among scientific institutions, ethical vigilance is a permanent necessity. Falsification of scientific results and the premature release of drugs on the market show that modern ethics does not in itself provide full protection against scientific misconduct, especially when it occurs beyond the critical step of malevolent or unsafe experiments involving human beings.

Bioethics experts Paul Weindling and Volker Roelcke suggest that current bioethical thinking may use an incomplete picture of the historical context of the Nuremberg code. Volker Roelcke writes: “*rather than being the result of a coercive state, Nazi medicine illustrates how medical researchers and their representative bodies [...] co-operated with and even manipulated a totalitarian state and political system relying on expert opinion, in order to gain resources for the conduct of research without any moral and legal regulation.*” He states that Nazi doctors “*followed the intrinsic logic of their scientific disciplines and used the legally and ethically unrestricted access to human beings created by the context of the political system and the conditions of war.*”⁴ By centring exclusively on the war crimes and not on their broader context, the judges at Nuremberg issued the code in order solely to set the boundaries for “*permissible experiments*” and tackle the difficult question of the biomedical research conducted on human subjects outside Germany during the war. The court thus failed to produce a broader

legal doctrine protecting individuals against harm induced by scientific practices at large, including not only human beings as subjects of medical experiments but also as consumers and beneficiaries of science's outcomes. ■

References

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4. Roelcke V, Maio G (ed.): *Twentieth Century Ethics of Human Subjects Research. Historical Perspectives on Values, Practices, and Regulations*, p. 162, Stuttgart, Franz Steiner Verlag, 2004.

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Committee be modified and license No. 71055 and license No. 37359 respectively, issued under date of March 21, 1951, to said Dr. Southam and December 1, 1939, to said Dr. Mandel, and their registration or registrations as physicians, wherever they may appear, be suspended for a period of 1 year on each specification, said suspensions to run concurrently from the date of the service of the order effecting such suspensions, but that the execution of such suspensions be stayed, and each respondent be placed on probation for a period of 1 year upon the following terms and conditions:

1. That each respondent shall conduct himself in all ways in a manner befitting his professional status and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession;
2. That so long as there is no indication of any further misconduct, each respondent may continue to practice as a physician, but the Department, upon receipt of satisfactory evidence of any such further misconduct, may forthwith terminate the stay of execution and order that the stay be vacated and the medical license of the respondent or respondents involved be suspended for a period of 1 year from the date of said order;
3. That any such action by the Department vacating the stay of the suspension as to either or both respondents shall in no way bar further disciplinary action based upon additional misconduct;

4. That each respondent shall notify the Department of any change of address or employment;
5. That upon full compliance with these conditions for a period of 1 year each respondent may apply to the Department for discharge from probation; and that the Commissioner of Education be empowered to execute, for and on behalf of the Board of Regents, all orders necessary to carry out the terms of this vote.

NOTE

AMERICAN ASSOCIATION FOR CANCER RESEARCH MINUTES OF THE 59TH ANNUAL MEETING*

The Annual Business Meeting of Members was called to order at 5:10 P.M., April 12, 1968, at Haddon Hall, Atlantic City, New Jersey by Vice-President Southam. . . .

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Dr. Southam announced that the tellers had informed him that Dr. Abraham Cantarow had been selected as the Vice-President of the Association for 1968-69. The Secretary-Treasurer said that the Board recommended that Dr. Chester M. Southam be elected President for 1968-69. When no additional nominations were made from the floor, it was moved that these two officers be declared duly elected. . . .

* 10 *Proceedings of the American Association for Cancer Research* 110-111 (1969). Copyright 1969 by Cancer Research, Inc. Reprinted by permission.

THE WILLOWBROOK HEPATITIS STUDIES

David J. Rothman and Sheila M. Rothman

The attempt to bar Willowbrook's hepatitis carriers from the public schools had a special irony to it, for from 1956 through 1971, researchers fed live viruses

to children in Willowbrook in order to study the disease and attempt to create a vaccine against it.

The head of the team was Saul Krugman. In appearance, he borders on the colorless, but controversy surrounds him. Krugman's research at Willowbrook brought him fame and power. He has chaired national committees on hepatitis, directed

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