USAFA Human Subjects Protection
The Code of Nuremberg

THE NUREMBERG TRIALS

"Early in 1946 the Allied Military Tribunal was preparing to try twenty-three Nazi physicians and scientists charged with performing cruel experiments on political prisoners. At the request of the Secretary of State and the Secretary of War, the American Medical Association appointed Dr. Andrew C. Ivy, of Chicago, to serve as adviser to the lawyers assigned to prosecute the defendants. Dr. Ivy was to consult with the prosecutors on the ethics of medical research. He drafted ten principles of ethics governing the use of human subjects in medical research. This code, with some modifications, was adopted as the cornerstone of the Allied cases against Nazi physicians. Presented during the trials by General Telford Taylor, it has become a significant guidepost in the Western world.

"The Nuremberg Code of Ethics on Medical Research was formally approved by the House of Delegates of the American Medical Association in 1946. Similar codes have been adopted by various medical societies throughout the world and by the World Medical Association. Although some of these codes include more detailed guidelines developed in the light of later experience, none adds substantively to the Nuremberg principles governing the use of human subjects in medical research. Building upon these principles, the Congress in 1962 amended the Food, Drug, and Cosmetic Act, legally requiring, for the first time, that an investigator of a new drug must obtain the informed consent of an individual to whom the drug will be administered. In 1966, the NIH established the rule that grantee institutions must set up committees to consider a research patient's rights, and to ensure the use of informed consent procedures." In 1974, the "Common Rule," 45 CFR 46 was adopted.

THE NUREMBERG CODE

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.

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 judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.