DECLARATION OF HELSINKI, 1964, Revised [Originally 1962]

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association (1964) binds the doctor with the words, "The health of my patient will be my first consideration"; and the International Code of Medical Ethics which declares that "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest."

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil, and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and clinical research the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research, and should be based on laboratory and animal experiments or other scientifically established facts. [The use of animals is not always feasible or possible.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. Clinical Research Combined with Professional Care

1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering.

If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. Non-therapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.

2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.

3c. Consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject, even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued. The investigator or the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.

Comment. Here, as in most other codes, the impossibility of knowing what the hazards will be in a new project—plus the frequent difficulties, even impossibility, of communicating the problems involved—are ignored. There is no facing up to the fre-

quently overwhelming difficulties in obtaining truly valid consent.

In actual fact in our society many kinds of human experimentation are often conducted by laymen; the introduction of a new type of plane constitutes a human, sometimes even a fatal experiment. Much psychological experimentation is carried out by psychologists; physicians often would not be competent to engage in it. A physician should, of course, supervise such aspects of psychological studies as the use of drugs.

The phrase in the first basic principle, ". . . research should be based on laboratory and animal experiments . . . ," cannot always be followed, certainly not generally in the study of mental disease and its treatment; neither can it be followed in study of disease not present and not producible in animals. Mead [296] makes an interesting comment in this area; there is in certain kinds of animal work the problem of ". . . how to control the tendency of the human observer to anthropomorphize, and so distort his observations."

The Nuremberg Code presents a rigid set of legalistic demands. In attempting to provide for all contingencies, it leaves the investigator badly exposed in two ways: (1) it is folly to suppose that every situation can be anticipated and provided for; (2) it asks for the impossible in several instances. These have been mentioned in the foregoing comment on the code. The Declaration of Helsinki, on the other hand, presents a series of guides. It is an ethical as opposed to a legalistic document, and is thus a more broadly useful instrument than the one formulated at Nuremberg. The Declaration of Helsinki separates professional care for the direct benefit of the subject from nontherapeutic research, which the Nuremberg Code does not. Until recently, the Western world was threatened with the imposition of the Nuremberg Code as a Western credo. With the wide adoption* of the Declaration of Helsinki, this danger is apparently now past.

* Among the organizations adopting it are the American Society for Clinical Investigation, the American College of Physicians, the American College of Surgeons, and the American Medical Association.