

GERMAN GUIDELINES ON HUMAN EXPERIMENTATION 1931

The following guidelines for therapeutic and scientific research on human subjects, which are thought to be the first of their kind, were published originally as a Circular of the Reich Minister of the Interior dated February 28, 1931. The guidelines remained in force until 1945, but were not included in the Reich Legislation validated at the end of World War II. It is interesting to note the disjunction between the guidelines and the practice of the Nazi researchers.

1. In order that medical science may continue to advance, the initiation in appropriate cases of therapy involving new and as yet insufficiently tested means and procedures cannot be avoided. Similarly, scientific experimentation involving human subjects cannot be completely excluded as such, as this would hinder or even prevent progress in the diagnosis, treatment, and prevention of diseases.

The freedom to be granted to the physician accordingly shall be weighed against his special duty to remain aware at all times of his major responsibility for the life and health of any person on whom he undertakes innovative therapy or performs an experiment.

2. For the purposes of these Guidelines, "innovative therapy" means interventions and treatment methods that involve humans and serve a therapeutic purpose, in other words that are carried out in a particular, individual case in order to diagnose, treat, or prevent a disease or suffering or to eliminate a physical defect, although their effects and consequences cannot be sufficiently evaluated on the basis of existing experience.

3. For the purposes of these Guidelines, "scientific experimentation" means interventions and treatment methods that involve humans and are undertaken for research purposes without serving a therapeutic purpose in an individual case, and whose effects and consequences cannot be sufficiently evaluated on the basis of existing experience.

4. Any innovative therapy must be justified and performed in accordance with the principles of medical ethics and the rules of medical practice and theory.

In all cases, the question of whether any adverse effects which may occur are proportionate to the anticipated benefits shall be examined and assessed. Innovative therapy may be carried out only if it has been tested in advance in animal trials (where these are possible).

5. Innovative therapy may be carried out only after the subject or his legal representative has unambiguously consented to the procedure in the light of relevant information provided in advance. Where consent is refused, innovative therapy may be initiated only if it constitutes an urgent procedure to preserve life or prevent serious damage to health and prior consent could not be obtained under the circumstances.

6. The question of whether to use innovative therapy must be examined with particular care where the subject is a child or a person under 18 years of age.

7. Exploitation of social hardship in order to undertake innovative therapy is incompatible with the principles of medical ethics.

8. Extreme caution shall be exercised in connexion with innovative therapy involving live microorganisms, especially live pathogens. Such therapy shall be considered permissible only if the procedure can be assumed to be relatively safe and similar benefits are unlikely to be achieved under the circumstances by any other method.

9. In clinics, polyclinics, hospitals, or other treatment and care establishments, innovative therapy may be carried out only by the physician in charge or by another physician acting in accordance with his express instructions and subject to his complete responsibility.

10. A report shall be made in respect of any innovative therapy, indicating the purpose of the procedure, the justification for it, and the manner in which it is carried out. In particular, the report shall include a statement that the subject or, where appropriate, his legal representative has been provided in advance with relevant information and has given his consent.

Where therapy has been carried out without consent, under the conditions referred to in the second Paragraph of Section 5, the statement shall give full details of these conditions.

11. The results of any innovative therapy may be published only in a manner whereby the patient's dignity and the dictates of humanity are fully respected.

12. Sections 4-11 of these Guidelines shall be applicable, *mutatis mutandis*, to scientific experimentation (cf. Section 3).

The following additional requirements shall apply to such experimentation:

(a) experimentation shall be prohibited in all cases where consent has not been given;

(b) experimentation involving human subjects shall be avoided if it can be replaced by animal studies. Experimentation involving human subjects may be carried out only after all data that can be collected by means of those biological methods (laboratory testing and animal studies) that are available to medical science for purposes of clarification and confirmation of the validity of the experiment have been obtained. Under these circumstances, motiveless and unplanned experimentation involving human subjects shall obviously be prohibited;

(c) experimentation involving children or young persons under 18 years of age shall be prohibited if it in any way endangers the child or young person;

(d) experimentation involving dying subjects is incompatible with the principles of medical ethics and shall therefore be prohibited.

13. While physicians and, more particularly, those in charge of hospital establishments may thus be expected to be guided by a strong sense of responsibility towards their patients, they should at the same time not be denied the satisfying responsibility (Verantwortungsfreudigkeit) of seeking new ways to protect or treat patients or alleviate or remedy their suffering where they are convinced, in the light of their medical experience, that known methods are likely to fail.

14. Academic training courses should take every suitable opportunity to stress the physician's special duties when carrying out a new form of therapy or a scientific experiment as well as when publishing his results.

[Encyclopedia of Bioethics, Ed. Warren T Reich 2nd Edition, Appendix p. 2762-2763]