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THE LEGAL REGULATION OF HUMAN EXPERIMENT ON THE BASIS OF THE NUREMBERG CODE AND THE DECLARATION OF HELSINKI

The Curiosity in human experiments dates back to ancient times, when the main and the most available source of information was to test the effectiveness of a drug or method directly on slaves (as objects). Over time, as human beings stopped to be a subject of enslavement, human experiments became increasingly human. However, a turning point in the history of human experiments was the 20th century. The new stage was begun with the condemnation and torture of human experiments of Nazi doctors in the concentration camps (the so-called Doctors' Trial).

The first result of the struggle against cruelty, inhumanity and mankind' desire to prevent similar crimes in the future was the Nuremberg Code (1947), both the first international and the most important document in the history, that was focused on the ethic aspect of medical research. The Code formulated a new standard of ethical medical behavior for human rights era after the World War II, which is expressed in 10 principles of carrying out of medical research on the human subjects [1].

The main principle of the Nuremberg Code is necessity to obtain the voluntary informed consent of the human subject in order to carry out an experiment. In other words, the person (potential human subject) should have the full legal capacity to give consent; should exercise free power of choice, without the intervention of any element of force, deceit, fraud, overreaching, duress, or other ulterior form of constraint or coercion. The principle of voluntary informed consent protects the individual's right to control his own body and it ensures that the human subject has all necessary knowledge and understanding of all details and peculiarities of the experiment in order to make an informed decision. Before experiment

is carried out, the human subject should know about the character, duration, and aim of the experiment; the method and means by which it is to be carried out; all inconveniences and hazards; and the consequences for the health (both physical and mental) or person which may be involved in the experiment [3, p. 2].

Moreover, the degree of risk of the experiment shouldn't exceed the humanitarian necessity, which should rich the experiment. Beside it, the human experiment, which can cause a disability or death, can't be carried out at all. The possibility to terminate the experiment at any stage by the wish of the human subject is foreseen.

The fundamental ideas of the Nuremberg Code have found their continuation, extension and development in the Declaration of Helsinki. The latter is a set of ethical provisions concerning human experiments for the medical community, which are formulated by the World Medical Association. But unlike The Nuremberg Code, the Declaration of Helsinki focuses on the obligations of physician-investigators to the human subjects, not just only on the human rights of the human subjects.

Speaking about the Declaration of Helsinki, "it is a legal act that determines the criteria for the lawfulness of the implementation of medical experiments. The document contains three sections:

1. Basic principles.

2. Medical research, which are combined with professional help (clinical research).

3. Nonclinical biomedical research with the involvement of human subject.

It contains important provisions concerning:

- prevention of risks during human experiments;
- full and timely informing of the human subject;
- observance of confidentiality of the human subject information;
- the principle of voluntary consent;
- timely and comprehensive application of the human subject protection mechanisms;
- protection of both safety and health of the human subject [4, p. 243].

In addition, Article 29 provided the possibility of obtaining consent of potential human subject who are physically or mentally unable to express consent, such as unconscious patients. In such circumstances, the doctor must obtain the informed consent from the legal representative of such human subject [2].

After numerous revisions (there was 7 times) of the Declaration, there is the shift of the unconditional dominance of individual health and the rights of human subjects to situation when we need to take into account the interests of society and populations.

Thus, the Nuremberg Code and the Declaration of Helsinki are the main international legal documents, which regulate ethic aspect of human experiments. Their fundamental provisions have great impact on relations in this sphere in general, as well as become a base for other national and international medical documents.

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