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ETHICAL AND LEGAL FOUNDATIONS OF HUMAN MEDICAL RESEARCH: DEVELOPMENT, GLOBAL STANDARDS, AND APPLICATION IN UKRAINE

Vasyl Biblenko,
PhD student at the Department of National, International Law, and Law Enforcement Activities of Kherson State University, Ukraine
orcid.org/0000-0003-3688-2458
biblenko1985@gmail.com

Summary. The article is dedicated to a comprehensive analysis of the ethical and legal foundations of medical research involving human participants, particularly focusing on their historical development, international regulation, and implementation in Ukraine. The authors highlight key historical events that became turning points in the formation of modern standards for the ethics of medical experiments, starting with the tragic experience of medical experiments conducted by Nazi doctors during World War II. Special attention is given to the Nuremberg Doctors' Trial (1946–1947), which for the first time raised the issue of the ethicality of medical experiments, and the adoption of the Nuremberg Code in 1947—the first document to define key ethical principles such as voluntary consent of participants, minimization of risks, and researchers' responsibility. The article examines the subsequent development of international regulation, including the Declaration of Helsinki (1964), which became the foundation for the formation of global standards for the ethical conduct of biomedical research. The article also analyzes the Council of Europe's Convention on Human Rights and Biomedicine (1997) and its additional protocols, which contain detailed requirements for protecting the rights of research participants, especially vulnerable populations. Particular attention is paid to the legal regulation of medical research in Ukraine, including the reflection of international standards in the country's legislation. The main regulatory legal acts, such as the Law of Ukraine "Fundamentals of Ukrainian Legislation on Healthcare," the Law of Ukraine "On Medicinal Products," and subordinate acts regulating the procedure for conducting clinical trials, have been analyzed. Emphasis is placed on the importance of adapting Ukrainian legislation to modern international standards, particularly regarding the protection of the rights of research participants, especially in the context of new challenges related to biotechnology and genome research. The importance of ethical principles in scientific activities is underscored, particularly the prioritization of participants' interests over the interests of science and society, as well as ensuring the right to voluntary informed consent. The article examines challenges associated with the introduction of new technologies in medical research, such as the use of human-derived biomaterials and cloning. The need to strengthen legal regulation in this area and to create effective control mechanisms is emphasized. In the conclusions, attention is drawn to the necessity of further improving Ukraine's regulatory legal framework, taking into account international experience, which will help ensure a balance between the development of science and the protection of human rights.

Keywords: medical research, bioethics, human rights, legal regulation, ethical principles.

1. Introduction

World War II became a critical moment in the history of human medical experiments. During this time, Nazi doctors conducted brutal experiments on concentration camp prisoners, including children, the elderly, and pregnant women. It is estimated that approximately 275,000 people died as a result of such "scientific" experiments. Historical sources also indicate that similar experiments were conducted by Japanese doctors (Ziablykov & Bezuhlov, n.d.).

Details about the cruel Nazi medical experiments became public only during the Nuremberg Doctors' Trial, which took place from December 1946 to August 1947. During this trial, twenty doctors and three organizers of medical experiments were held accountable (Cohen, n.d.).

The main charges included forced medical experiments, the killing of prisoners to create Hirt's skeleton collection (HMN.WIKI, n.d.), forced euthanasia, sterilization experiments, and much more (NI.BIZ.UA, n.d.). However, these tragic events became a turning point in the history of medical research, prompting a review of approaches to the safety of research involving humans and raising questions about the protection of the rights of research subjects.

2. International Standards of Ethics in Medical Research

In response to these events, the "Nuremberg Code" was created in 1947, marking the first formal record of ethical and legal principles for conducting medical research on humans. A total of ten principles were outlined, including voluntary consent of the participant, the societal benefit of the research, scientific justification, minimization of physical and psychological suffering, the absence of the likelihood of causing

death or disability, prioritizing the societal importance of the research over risks, the availability of appropriate preparation and equipment, the requirement of scientific qualification for researchers, the participant's right to withdraw from the study, and the researcher's obligation to terminate the study under certain circumstances. Although the provisions of the Nuremberg Code were not legally binding and were more of ethical guidelines, the document became a significant step in regulating medical research involving humans. It was the first indication that scientific activity requires ethical and regulatory limitations (The Nuremberg Code, 1947).

Later, repeated cases of illegal human experimentation prompted the global community to develop effective legal mechanisms to protect the rights and interests of research subjects at both international and national levels. In this context, the World Medical Association (WMA), founded in 1946, played a particularly important role (World Medical Association, n.d.-a). By 1953, members of the Association had already expressed the necessity of developing ethical guidelines for conducting research on humans.

At the General Assembly of the WMA in Rome in 1948, the resolution "Principles for Conducting Research and Experiments" was adopted, based on the Nuremberg Code (The Nuremberg Code, 1947). In 1961, the WMA Ethics Committee formulated a draft Code of Ethics for experiments on humans and presented it at the WMA General Assembly in Rio de Janeiro. After discussing this draft at the WMA General Assembly in Helsinki in 1964, a document was adopted, which is now known as the Helsinki Declaration (World Medical Association, 1964).

The document in question is an important guide for medical professionals engaged in biomedical research involving humans. The Helsinki Declaration, adopted at the international level, contains key principles that states must adhere to when organizing such research. Among the main provisions are the necessity of scientific justification for the research, the qualification of the specialist conducting it, the prioritization of the participant's interests over the interests of science and society, ensuring the right to personal integrity, and the requirement to obtain voluntary informed consent from the participant. The participant also has the right to withdraw from participation at any time (World Medical Association, 1964).

The Declaration also introduced, for the first time, a clear distinction between clinical research related to medical care and non-clinical research of a purely scientific nature, establishing general and specific conditions for their conduct (World Medical Association, 1964).

3. Legal Regulation of Medical Research in Ukraine

In Ukraine, the principles outlined in the Helsinki Declaration are reflected in a number of national legislative and regulatory acts that govern the procedure for conducting medical research on humans. The key regulatory documents in this field include the Law of Ukraine "Fundamentals of Ukrainian Legislation on Health Protection" (Verkhovna Rada of Ukraine, 1992), the Law of Ukraine "On Medicinal Products" (Verkhovna Rada of Ukraine, 2022), and the Order of the Ministry of Health of Ukraine "On Approval of the Rules for Conducting Clinical Trials of Medical Equipment and Medical Devices and the Model Regulation on the Ethics Committee" (Ministry of Health of Ukraine, 2012).

In 2000, the Helsinki Declaration was updated, introducing significant changes to its content. The Declaration, which originally contained 32 articles, was revised so that only three articles remained unchanged, and eight were added for the first time. Among the key innovations were the expansion of the Declaration's scope, now including research on human-derived biomaterials. Measures to protect vulnerable population groups were also strengthened, and the amount of information researchers are required to provide to the Ethics Committee was increased (World Medical Association, 1964).

The Convention on Human Rights and Biomedicine, adopted in 1997, differs from the Helsinki Declaration in that it contains mandatory norms for the countries that have signed and ratified it (Council of Europe, 1997). Chapter V of the Convention addresses scientific research, and the requirements for conducting research on humans are presented in greater detail than in the Helsinki Declaration. In particular, the Convention emphasizes so-called "vulnerable" population groups, providing them with additional guarantees of protection. Furthermore, the document specifies additional conditions that must be met during experiments that do not bring direct health benefits to participants. The Convention also takes into account modern scientific developments and includes provisions aimed at protecting human embryos (Council of Europe, 1997).

Over time, Additional Protocols were added to the foundational document, the Convention on Human Rights and Biomedicine, which clarify and expand regulations in this field. These protocols, adopted in different years, cover a broad range of issues, from the prohibition of human cloning to norms regarding organ transplantation and biomedical research (Council of Europe, 2005).

The Protocol on Biomedical Research, in particular, establishes detailed requirements for the organization and conduct of research, including those that may pose risks to the mental health of participants. An important part of this document is the establishment of a list of information that must be provided to the Ethics Committee for evaluating a research project, as well as the specification of data that must be disclosed to research participants (Council of Europe, 2005).

Special attention in the Protocol is given to protecting such categories of participants as pregnant women, breastfeeding mothers, prisoners, and individuals in critical health conditions. Research involving these groups is permitted only under strict adherence to certain conditions (Council of Europe, 2005).

The issue of human cloning has sparked intense reactions and debates within the scientific community, particularly in the context of reproductive and therapeutic cloning. This has necessitated the creation of clear legal frameworks, both at the international level and within the national legislation of individual countries, to regulate these complex and sensitive issues.

In Ukraine, a law was adopted that establishes a prohibition on human reproductive cloning, which is an important step in the regulation of bioethical issues (Verkhovna Rada of Ukraine, 2004).

4. Modern Challenges and Prospects for Legal Regulation

At the international level, there are also documents aimed at protecting the genetic identity of both individuals and entire ethnic groups. One such document is the Universal Declaration on the Human Genome and Human Rights, adopted in 1997 (UNESCO, 1997). This Declaration emphasizes the importance of preserving genetic uniqueness, prohibits any form of manipulation with human genes, including cloning, and simultaneously encourages scientific research in the field of genomics (UNESCO, 1997). Such measures are an integral part of creating a reliable legal foundation to ensure the ethical aspect of medical research and the protection of human rights in the era of biotechnological innovations.

In the field of legal regulation of medical research on humans and embryos, there are numerous international acts covering a wide range of issues, from artificial insemination to tissue transplantation. These documents range from advisory provisions to binding directives that establish standards for clinical practice and the protection of research participants' rights. Among them are the Regulations on In-Vitro Fertilization and Embryo Transplantation of 1987 (Khmara, 2020 : 22), the Regulations on Genetic Counseling and Genetic Engineering of 1987 (Verkhovna Rada of Ukraine, n.d.), the Regulations on the Transplantation of Fetal Tissues of 1989 (World Medical Association, 1989), the Recommendation of the Council of Europe No. 1046 on the Use of Embryos for Diagnosis, Therapy, Scientific Research, Industrial Use, and Trade of 1986 (Council of Europe, 1986), the Recommendation of the Committee of Ministers No. R(90)3 to Member States on Medical Research on Humans (Council of Europe, 1990), and the Directive 2001/20/EC of the European Parliament and of the Council of April 4, 2001, on the Approximation of the Laws, Regulations, and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use (European Parliament and Council of the European Union, 2001), among others.

5. Conclusions

In the field of legal regulation of medical research on humans and embryos, there are numerous international acts covering a wide range of issues, from artificial insemination to tissue transplantation. These documents range from advisory provisions to binding directives that establish standards for clinical practice and the protection of research participants' rights.

It is important to emphasize that, over time, the international community has recognized the necessity not only of regulation but also of establishing accountability for violations in this sensitive area. In some countries, the process of criminalizing actions related to unlawful experiments on humans reached its peak at the end of the 20th and the beginning of the 21st century, reflecting the seriousness of the approach to protecting human rights in the context of biomedical research. This trend has been embodied in legislation, particularly in the criminal codes of many European countries and beyond.

The development of legal frameworks for biomedical research continues to evolve, addressing modern challenges such as genetic engineering, cloning, and the use of artificial intelligence in medicine. These advancements require constant updates to international and national legislation to ensure the ethical and legal protection of research participants while fostering scientific progress.

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