REVIEW ARTICLE

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Legal regulation of biomedical research: key principles and their implementation

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ABSTRACT

Aim: To analyze the key principles underlying the legal regulation of biomedical research and evaluate their practical implementation in contemporary legal frameworks.

Materials and Methods: This study employs a comprehensive literature review, including academic publications, legal documents, and international guidelines on biomedical research ethics. Qualitative analysis identified core principles of legal regulation. Comparative legal analysis assessed principle implementation across jurisdictions. Case studies of biomedical research projects provided practical insights. A systematic review of ethical committee reports and policy documents highlighted implementation challenges and best practices.

Conclusions: Ethical principles in biomedical research form a complex framework essential for protecting participants' rights while advancing science. A shift from paternalistic models to patient autonomy is evident, yet implementation challenges remain, particularly in balancing information disclosure with potential negative impacts. Evolving biomedical technologies necessitate ongoing principle refinement. Future efforts should focus on improving complex medical information communication, ensuring informed decision-making, addressing vulnerable populations' needs, while maintaining balance between individual rights and societal benefits. Attention is paid to the principle of informed consent, which is fundamental to modern bioethics and medical practice, reflecting the transition from a paternalistic model to a model emphasizing patient autonomy.

KEY WORDS: biomedical research, human rights, informed consent, personal autonomy, ethical principles

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INTRODUCTION

In light of the rapid development of biomedical technologies and their growing impact on society, the issue of legal regulation of biomedical research is becoming particularly relevant. These studies, aimed at expanding the boundaries of scientific knowledge and improving the quality of people's lives, at the same time give rise to a number of ethical and legal challenges. In particular, they relate to ensuring the rights and freedoms of research participants, preserving their dignity and inviolability of private life [1].

Legal regulation of biomedical research is based on a number of key principles designed to harmonize the interests of scientific progress and protection of human rights. These principles cover a wide range of aspects: from ensuring the autonomy of the will of research participants to preserving the confidentiality of the obtained data. They form the foundation for the development of regulations and ethical codes in the field of biomedical research, defining the limits of permissible intervention in the human body and psyche [2].

The implementation of these principles in practice requires the creation of effective mechanisms of control and supervision over the conduct of biomedical research. This involves not only the legislative establishment of relevant norms, but also the formation of a system of ethical committees, the development of informed consent procedures, the establishment of clear criteria for assessing risks and potential benefits from research. Thus, legal regulation in this area should be flexible and adaptive, capable of responding to new challenges that society faces in connection with the development of biomedical technologies [3].

AIM

The aim of this research is to analyze the key principles underlying the legal regulation of biomedical research and evaluate their practical implementation in contemporary legal frameworks.

MATERIALS AND METHODS

This study employs a comprehensive review of relevant literature, including academic publications, legal documents, and international guidelines on biomedical research ethics. A qualitative analysis of these sources was conducted to identify and examine the core principles of legal regulation in biomedical research. Additionally, comparative legal analysis was used to assess how these principles are implemented in various jurisdictions, with a focus on national legislation and international conventions. Case studies of notable biomedical research projects were also analyzed to provide practical insights into the application of these legal principles. The research methodology also included a systematic review of ethical committee reports and policy documents to understand the challenges and best practices in implementing these principles.

REVIEW AND DISCUSSION

Legal regulation of biomedical research is based on a number of fundamental practical principles. Let's take a closer look at one of the key ones among them.

The principle of respect for individual autonomy is the cornerstone of the modern approach to biomedical research. According to J. Hans, this principle reflects a paradigm shift in the role of patients and research participants in modern biomedicine. The essence of this principle is the recognition of a person's capacity for independent, independent thinking and decision-making regarding participation in research and assessment of its potential consequences. A critically important aspect of the implementation of this principle is the creation of conditions under which the research participant is protected from any form of psychological pressure or manipulation, including covert ones. For example, it is unacceptable to create artificial interest or use other methods of indirect influence on a person's decision. Ensuring true freedom of choice is not just an ethical norm, but a necessary prerequisite for the legitimacy and validity of biomedical experiments with human participation [4].

The historically formed paternalistic model of domestic medicine was based on the presumption that the right to make decisions belongs exclusively to medical specialists, while the patient's opinion was considered incompetent and often ignored. This trend still persists in the Ukrainian health care system, where there is a certain resistance to the active involvement of patients in the decision-making process regarding their treatment or participation in medical research.

However, it is important to realize that such practices, which disregard the principle of individual autonomy, are not only ethically questionable, but also potentially threaten the fundamental interests of the patient or research participant. By placing a person in a subordinate position, we not only violate his moral rights, but also create a situation where his vital interests can be ignored or misinterpreted.

Therefore, the transition from a paternalistic model to a model based on respect for individual autonomy is not only an ethical imperative, but also a necessary condition for ensuring quality and safe medical care and conducting ethically based biomedical research [5].

The principle of respect for human dignity is the cornerstone of the ethical system that regulates social interactions. This complex concept covers a wide range of moral and ethical aspects of interpersonal relations in society. It manifests itself through a number of key behavioural patterns, such as:

1. Manifestation of benevolence in communication and actions;
2. Demonstration of respect for the diversity of thoughts and actions of others;
3. Compliance with norms of correctness in interaction;
4. Cultivation of politeness as a basic form of social communication.

This principle serves as a fundamental guideline for the formation of a healthy society where every individual is valued and respected regardless of their status or beliefs [6]. In the context of medicine in general, and especially in the field of biomedical research involving humans, the principle of respect for human dignity acquires special importance. It defines the nature of the interaction between the healthcare professional (or researcher) and the patient (or research participant) while maintaining all the above-mentioned characteristics. It is important to emphasize that compliance with this principle is not only desirable, but absolutely necessary: without it, it is impossible to conduct ethically acceptable biomedical research, as well as to build an effective health care system in general [1].

However, despite the obvious importance of this principle, its implementation in modern society often faces serious challenges. Particularly alarming is the tendency to objectify the human body, when it or its parts are viewed as a commodity or a thing. Clear examples of this are the discussions on the commercialization of organ and tissue donation, or the problem of prostitution. Such phenomena lead to a dangerous shift in public consciousness, where the human body begins to be equated with other objects of the material world, which contradicts the fundamental principle of respect for human dignity [7].

When conducting biomedical research involving a person, it is critically important to realize that the

object of research is not just biological material, but a whole person with his life and health. This concept is enshrined as the highest value in the Constitution of Ukraine and key international legal acts. The principle of respect for human dignity requires a special, respectful attitude towards a person and his bodily integrity. It is important to emphasize the universality of this principle: human dignity is an integral characteristic of every person, regardless of their individual characteristics or social status. This universality means that respect for human dignity cannot be conditioned or limited by factors such as ethnicity, skin color, religious beliefs, socio-economic status, health status or any other external characteristics. Thus, in the context of biomedical research, this principle provides an equal and ethical approach to all participants, regardless of their individual characteristics [8].

The principle of utility in biomedical research is a multidimensional concept that encompasses potential benefits both for the direct participants of the research and for society as a whole. A central aspect of this principle is a careful analysis of the relationship between the potential risks and the expected benefits of the research. Assessing the admissibility of such a ratio requires a comprehensive approach, which includes:

1. Comprehensive analysis of all aspects of research;
2. Systematic consideration of alternative methods and approaches;
3. Detailed study of all available information related to the study.

It is critical that assessments of potential harm consider not only the obvious physical and psychological risks to participants, but also all possible forms of negative impact. This may include social, economic, legal and other aspects that may affect the well-being of research participants or society as a whole. Thus, the principle of usefulness requires a multifactorial analysis and a balanced approach to assessing the ethical acceptability of biomedical research [9].

The principle of utility, which is fundamental in the regulatory regulation of biomedical research involving human subjects, requires a careful balancing of potential risks and expected benefits. The analysis of relevant international and national legal norms allows us to identify key criteria for assessing the ethics and legitimacy of such research. These criteria include the uniqueness and scientific significance of the research, its ethical optimization, scientific validity, a positive balance of risk and benefit, full awareness of both researchers and participants about possible consequences. Compliance with these criteria ensures not only scientific progress, but also protects the rights and safety of research participants, which is a key aspect of modern bioethics [10].

The principle of voluntary informed consent is a cornerstone of modern bioethics and medical practice. This principle not only protects against "medical tyranny" and ensures personal freedom, but also promotes an informed decision by the research participant, aware of the potential consequences of medical intervention or lack thereof. The concept of informed consent is a relatively new phenomenon in medical ethics. Historically, many physicians have taken a paternalistic approach, preferring to withhold from patients full information about their health and treatment. This practice was based on the belief that such information could harm the patient or complicate the treatment process. However, modern medical science and health care practice recognize the principle of informed consent as fundamental. It has become one of the key criteria for observing the rights of research participants and patients in general. This reflects a significant shift in medical ethics from paternalism to a model that emphasizes patient autonomy and their right to full information and participation in decisions about their own health and treatment. [11].

In the context of biomedical research, the principle of informed consent requires that the potential participant be provided with sufficient information to make an informed decision about participation. This information should include a detailed description of the aims, objectives and methodology of the study, a clear explanation of potential risks and expected benefits, a description of alternative options (especially in the case of therapeutic studies), as well as an explanation of the participant's right to ask questions and refuse participation at any time. what stage Information should be provided in a standardized, understandable form and be as complete as possible. Exceptions allowing incomplete disclosure of information are possible only when it is necessary to achieve the purpose of the study, under the condition of minimal undisclosed risks and with the guarantee of further full information of the participants. Such exceptions should be used with extreme caution in order not to violate ethical standards and the rights of research participants [11].

The principle of truthfulness in biomedical research is based on the need for honest and open dialogue between researchers and participants, while recognizing the difficulty of balancing full disclosure and maintaining some degree of confidentiality. This principle recognizes that while truthfulness is the foundation of social cooperation and trust, full disclosure of all information is not always appropriate or ethical. Understanding the difference between telling the truth and telling the whole truth is key, as well as recognizing the need for confidentiality in certain situations. The

ethical approach to truthfulness in research is based on two fundamental principles: the prohibition of lying and the limitation of revealing the truth only to those who have the right to it, which requires careful ethical analysis in each specific case [8].

In the context of biomedical research, the patient's right to information to provide informed consent is fundamental. However, a particularly complex ethical and legal situation arises in the case of placebo studies. The key question is whether the use of a placebo can be considered wrongful deception of the research participant. The decisive factor here is the method of informing about participation in such a study. If a participant is told that he will receive a drug that is potentially effective in this case and has no harmful side effects, this cannot be clearly interpreted as deception. With this wording, the participant receives enough information to provide informed consent, without violating the principle of truthfulness. Thus, the key is to provide the participant with all the necessary information without hiding important details, but also without revealing those aspects that could affect the reliability of the research results [6].

The principle of justice in the context of biomedical research is one of the most complex and important ethical aspects. The selection of research participants must be guided by the fundamental legal concepts of equality, impartiality and independence. However, the implementation of this principle is often complicated by the subjective understanding of the very concept of "justice", which can lead to social and interpersonal conflicts. Justice as a category serves as a measure of social reality, determining what should be preserved and what should be changed. It covers a wide range of relationships between the individual and society, various social groups, and deeply characterizes human activity. This concept requires a balance between the practical activities of individuals or groups and their social status, between rights and obligations, work and reward, personal achievements and their social recognition. Any violation of this balance is perceived by society as a manifestation of injustice.

In the context of biomedical research, the principle of equity should ensure equal access to research participation, fair distribution of risks and potential benefits, and protection of vulnerable populations from exploitation. This requires careful ethical analysis and ongoing monitoring to ensure that research does not exacerbate existing social inequalities or create new ones [12].

The principle of preserving medical secrecy is fundamental in medical ethics and legal practice. It prohibits the disclosure of professional information obtained during the study without the explicit permission of the participant. The importance of this principle is underscored by statutory protections, which in many cases give healthcare professionals the right not to disclose confidential information, even in court proceedings. This principle means that a doctor or researcher has no right to disclose any information about health status, disease characteristics or other medical data obtained confidentially from a patient or research participant without their express consent. This strict adherence to confidentiality is critical because unauthorized disclosure of medical information can lead to serious negative consequences for the individual, including social stigmatization, discrimination, psychological trauma, and disruption of personal and professional relationships. Preserving medical confidentiality not only protects the individual's privacy, but also promotes the establishment of trusting relationships between the doctor/researcher and the patient/participant, which is a necessary condition for effective treatment and conducting quality medical research [13].

According to European standards, information that a research participant provides to a doctor during a biomedical study is classified as "sensitive" data. As a general rule, such information is considered confidential and cannot be disclosed without the express consent of the participant.

However, there are exceptions to this rule. In certain situations, the disclosure of such information may be necessary to protect the interests of the state or society as a whole. This dichotomy between the protection of individual privacy and the potential need for disclosure in the public interest creates a complex ethical and legal dilemma. Such a situation emphasizes the importance of constant rethinking and improvement of both theoretical foundations and practical mechanisms for implementing the principle of preserving medical confidentiality. This requires a careful balance between the right to privacy, the need to ensure trust in the doctor-patient relationship, and the potential public interest that may justify the disclosure of confidential information in exceptional cases.

The importance of maintaining the confidentiality of medical information is most clearly manifested in cases where patients' trust in the health care system is undermined. A case in point is the situation with teenagers infected with sexually transmitted diseases (STDs). When the legislation obliged medical professionals to inform parents of minors about cases of STDs, this led to unforeseen negative consequences. Infected teenagers, fearing disclosure of information to their parents, avoided seeking medical help. This not only left them without proper treatment, but also contributed to the further spread of infections, which in some countries led to epidemic outbreaks.

The loss of trust in the health care system due to privacy violations has transformed into a serious public health problem. Only after the revision of the legislation and the restoration of the principle of confidentiality did the situation begin to improve. The guarantee of medical confidentiality encouraged young people to seek medical help, which significantly contributed to curbing the spread of STDs. This example clearly demonstrates how compliance with the principle of confidentiality in medicine not only protects the rights of individual patients, but also plays a key role in ensuring the effectiveness of the health care system and preserving public health as a whole [5].

The principle of privacy in the context of biomedical research is a fundamental ethical and legal norm. It categorically prohibits researchers from interfering in the private lives of research participants without their express consent, even if such interference is motivated by scientific interests. This principle is based on the understanding of man not only as a social being, but also as a unique individual with his own individuality. Recognition and protection of this individuality, as well as the right to privacy, are key aspects of respect for human dignity. A society that values and protects the privacy of its members thereby recognizes for them a certain degree of personal freedom. This freedom includes the right to control information about oneself, to decide who and to what extent can access personal data and aspects of an individual's life.

It is important to emphasize that respect for privacy and ensuring the inviolability of personal life are not just ethical norms, but necessary conditions for the functioning of a democratic society and the rule of law. They create a basis for the realization of other fundamental rights and freedoms, promote the development of individual autonomy and protect against unjustified interference by the state or other entities. In the context of biomedical research, compliance with the principle of privacy is particularly important, as such research often involves access to sensitive personal information. This requires researchers not only to obtain informed consent, but also to be constantly vigilant in maintaining data confidentiality and respecting the personal boundaries of research participants [3].

The concepts of "personal integrity" and "private life" are integral components of the broader concept of "individual freedom". These concepts are not just interconnected, but also logically follow from the principle of individual freedom. True individual freedom includes two key aspects:

1. Protection against illegal and violent state interference in a person's private life.
2. Guarantees of protection of life, honor, dignity and personal safety of every member of society.

It is important to note that the right to privacy is not absolute. Its limitation is possible, but only in cases clearly provided for by law. This ensures a balance between individual rights and public interest. The autonomy of the individual from the state, society or any social group is based on the guarantee of confidentiality of certain aspects of a citizen's private life. Without such a guarantee, true autonomy is impossible.

The legislation of Ukraine is aimed at:

1. Consolidation of legally defined procedures for the realization of privacy rights.
2. Creation of mechanisms to prevent violations of these rights.
3. Establishment of a procedure for the protection and restoration of violated rights and freedoms.
4. Determination of permissible limits of interference in private life by other persons, society and the state.

Thus, the legal system of Ukraine strives to create a comprehensive privacy protection mechanism that would ensure a balance between individual rights and public interests, while guaranteeing the fundamental freedoms of every citizen [13].

The principle of non-interference in private life is based on an understanding of the potential harm that may arise from the disclosure of personal information. In the context of biomedical research, two types of particularly sensitive information can be distinguished:

1. Personal information: data about private life, marital status, personal beliefs, etc.
2. Professional information (medical confidentiality): medical data, diagnoses, examination results.

Disclosure of these types of information without an individual's consent can lead to serious negative consequences, including social stigmatization, discrimination, psychological trauma, and disruption of personal or professional relationships.

When publishing research results, it is important to distinguish between two types of data:

1. Statistically summarized data: This information does not contain individual characteristics of the study participants. Its publication usually does not require a separate permission, as it does not carry the risk of identifying specific individuals.
2. Specific clinical cases: Such data may contain detailed personal and medical information. For their publication, it is necessary:

a) Obtain explicit permission from the research participant.
b) Take steps to anonymize data to minimize the risk of personal identification.

Adherence to these principles ensures a balance between the scientific value of the research and the protection of the privacy of the participants. This is not only

an ethical requirement, but also an important condition for maintaining public trust in medical research and the health care system as a whole [14].

CONCLUSIONS

1. Legal regulation of biomedical research is based on key ethical principles, such as respect for individual autonomy, respect for human dignity, utility, voluntary informed consent, truthfulness, fairness, medical confidentiality and privacy.
2. The implementation of these principles requires the creation of effective control and supervision mechanisms, including the formation of a system of ethical committees, the development of informed consent procedures and the establishment of clear criteria for assessing risks and potential benefits from research.
3. Particular attention is paid to the principle of informed consent, which is fundamental to modern bioethics and medical practice, reflecting the transition from a paternalistic model to a model emphasizing patient autonomy.
4. Preserving the confidentiality of medical information and respecting the privacy of research participants are critically important aspects that not only protect the rights of individuals, but also contribute to maintaining public trust in medical research and the health care system as a whole.
5. Legal regulation in the field of biomedical research should be flexible and adaptive, able to respond to new challenges associated with the development of biomedical technologies, while ensuring a balance between scientific progress and protection of the rights and safety of research participants.

REFERENCES

1. Hromovchuk M, Brych V, Sabadosh M. Euthanasia: some aspects of bioethics. Visegrad Journal on Human Rights. 2019;4:33-38.
2. Bielov DM, Petsa DD, Svyshcho VY, Novytsky VV. The human right to transplantation of organs and tissues: medicine, ethics and law. Wiad Lek. 2022;15(10):2519-2525. doi: 10.36740/WLek202210138. DOI
3. Bielov DM, Hromovchuk MV, Hreca YaV, Tymchak VV. Essence of somatic human rights in the process of biomedical research. Wiad Lek. 2021;14(10):2663-2668. doi: 10.36740/WLek202110226. DOI
4. Hans J. Philosophical Reflections on Experiments with Human Subjects. Experimentation with Human Subjects. ed. by P. A. Fraund. George Braziller Inc. 1979, p.529.
5. Hromovhcuk M. Human Rights for Life: selected aspects. Visegrad Journal on Human Rights. 2017;2:39-46.
6. Ostrovska BV. Dobrovilna informovana zghoda na biomedychni vtruchannia yak skladova prav liudyny. Filosofski ta metodolohichni problemy prava. [Voluntary informed consent to biomedical interventions as a component of human rights]. 2018. https://elar.naiau.kiev.ua/items/b73ef4e7-b0c2-4211-86a9-4ae0727311f1 [Accessed 10 January 2024] (Ukrainian)
7. Hromovchuk M, Bielov D. Euthanasia as legal category. Baltic Journal of Economic Studies. 2019;5(3):59-66.
8. Belorusov DYu, Yefimtseva TK, Maltsev VI. Eticheskiye printsipy provedeniya klinicheskikh issledovaniy [Ethical principles of clinical research]. Ukrainskyi medychnyi chasopys. 2001;5(25):66–80. (Ukrainian)
9. Stetsenko SH. Medychne pravo. [Medical law]. K. 2018, p.572. (Ukrainian)
10. Hromovchuk M. Euthanasia and bioethics: correlation issues. Visegrad Journal on Human Rights. 2020;5:76-80.
11. Tereshkevych HT. Informovana zghoda ta eksperymentuvannia nad liudynoiu [Informed consent and human experimentation]. Medychne pravo Ukrainy: pravovyi status patsiientiv v Ukraini ta yoho zakonodavche zabezpechennia (henezys, rozvytok, problemy i perspektyvy vdoskonalennia). Materialy II Vseukrainskoi naukovo-praktychnoi konferentsii 17-18.04. m. Lviv. 2008, p.511. (Ukrainian)
12. Bandura OO. Systema tsinnostei prava ta yii pryrodni pidvalyny (osnovni rysy) [The value system of law and its natural foundations (main features)]. Antropolohiia prava: filosofskyi ta yurydychnyi vymiry. Materialy Mizhnarodnoho «kruhloho stolu» (m. Lviv, 3-5 hrudnia 2010 roku). Lviv: "Halytskyi drukar", 2010, pp.45-53. (Ukrainian)
13. Bachynskyi VT. Likarska taiemnytsia: poniattia ta medyko-pravove zabezpechennia v Ukraini [Medical confidentiality: concepts and medical and legal protection in Ukraine]. Visnyk VDNZU «Ukrainska medychna stomatolohichna akademiia». 2014;4(52):293–297. (Ukrainian)
14. Tkach OV. Mezhi vtruchannia v pryvatne zhyttia osoby v kryminalnomu protsesi Ukrainy [Limits of interference in a person's private life in the criminal process of Ukraine]. URL: http://www.irbis-nbuv.gov.ua/cgi-bin/irbis_nbuv/cgiirbis_64.exe?I21DBN=LINK&P21DBN=UJRN&Z21ID=&S21REF=10&S21CNR=20&S21STN=1&S21FMT=ASP_meta&C21COM=S&2_S21P03=FILA=&2_S21STR=Nzlubp_2014_12_55 [Accessed 20 March 2024] (Ukrainian)

CONFLICT OF INTEREST

The Authors declare no conflict of interest

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