

BIOETHICS IN THE CONTEXT OF SOCIO-ECONOMIC, SOCIO-POLITICAL AND CULTURAL DEVELOPMENT OF SOCIETY

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Annotation – The paper considers the problems of ethical and legal regulation of modern biomedical research, where one of the methods of studying and describing environmental objects is an experiment. It is a key tool of practice, without which theory is impossible. Given the pace of development of modern science and the world as a whole, the topic of studying the principles of regulation of biomedical research and their improvement is relevant. The article highlights the basic principles of the use of humans and animals in biomedical research. It was explained why it is so important to strengthen the humanization of this process. The conclusions are the following: it is very important to prevent cruelty of any biological objects in the context of resolving bioethical and legal problems associated with the implementation of the principle of humanism and the protection of the rights of living organisms. Modern science and the practice of preclinical and clinical tests should be involved into serious challenge in order to improve and universalize the process of medical and biological research technology in vitro. The purpose of the article is to study the main international legal principles of using living organisms in biomedical experiments, as well as to determine the main problems on this issue and to outline the ways to resolve them. To examine the current state of ethical and legal regulation, principles and rules for conducting experimental biomedical research. Nowadays the international community has adopted enough legal acts regulating the proper behavior with biological objects, including those specially cultivated for such studies (laboratory) when conducting biomedical experiments. Recently, both, in the national legislation of European countries and international legislation, there have been trends to strengthen their protection in the field of biomedical research. The article provides examples of bullying, and as a result of a direct violation of the basic principles of bioethics – respect for the autonomy and dignity of a person. It is proved that the main task of bioethics is to preserve the life and health of every organism. It is imperative, both at the international and national levels, to adopt programs for development and support of scientific study of the in vitro biosystems introduction into research practice. At the national level, it is necessary to criminalize the violation of international standards for conducting biomedical research using organisms. Both, international and national legislation should impose a direct ban on the use of in vivo technologies in case of the possibility of using in vitro technologies.

Keywords: bioethics, medical ethics, morality, regulation, biomedical research.

I. INTRODUCTION

The more science seeks to serve the interests of mankind, the more it takes the form of technology, which consists in experiments on living objects. The implementation of evidence-based medicine standards, the development of new technologies and treatment methods, require a sufficient study of their safety and effectiveness and are documented. Problems of bioethics are widely discussed in modern literature, mainly philosophical, medical and legal. But its institutional status remains unclear. The current state of bioethics in the world is associated mainly with scientific advances [1]. At the same time, its regulatory role in society presupposes the existence of a certain system of organizations, a documentary base, and some invariant training of qualified personnel. These

three components form the structural basis of the institutionalization of bioethics. The functional side of this process includes the formation of a specific field in the context of social life, which regulates the impact of bioethical norms and principles. There is a collision that is rarely resolved. The normative nature of bioethical principles cannot, by definition, be formalized. This is most evident in the activities of ethics committees of medical institutions, which must resolve conflict situations, but these decisions are not binding on social services and administrative structures [2]. A similar situation exists with the adoption of national and international documents on bioethics, the application of which is limited. Thus, the idea of the value of life as a central problem of bioethics remains desirable, but its actualization depends on other factors beyond the competence of the bioethical community. Therefore, the only

reliable way out is to legally consolidate the institutional components of bioethics mentioned above.

II. FORMULATION OF THE PROBLEM

Analysis of research, production and practical activities of institutions, organizations and enterprises that relate to biological objects (including humans) and are subject to ethical and legal regulation. Substantiation of expediency and limits of regulation (including prohibitions, control, etc.) of research and practical human activity in the context of biological, pharmaceutical and medical ethics. Examples of neglect of personal safety and dignity of researchers and subjects for the sake of scientific discoveries in biology and medicine. Transformation of moral norms and cultural and religious principles into legal norms (national legislation in the field of bioethics, as well as relevant legislation of other countries).

III. THE AIM

Review of the current state of ethical and legal regulation, principles and rules of experimental medical and biological research. To consider the main functions and tasks of the ethics committee as one of the main mechanisms of ethical and legal regulation of biomedical experiments. Give examples of experiments for the sake of science on living objects (animals, humans). Prove that the main task of bioethics is to preserve life, respect for the autonomy and dignity of each individual.

IV. REGULATORY LEGAL NORMS (ETHICAL AND LEGAL REGULATION)

The widespread development of biomedical technologies and bioethical concepts is a relatively recent phenomenon. As a political-legal and socio-philosophical phenomenon, these technologies are part of scientific reflection (legal, political science, sociology, medicine) in the middle of the twentieth century. Thus, within the framework of legal science, legal regimes related to the management of human life processes are worked out. Here, the legal regulation is focused primarily on ensuring the fourth and fifth generations of human rights and the protection of his physical and spiritual freedom from the intensive development of biomedical knowledge, which in the twentieth century. reached the highest level. Modern biometric technologies not only save lives, but also have the ability to give life (eg, artificial insemination), artificially shape

and influence its natural and qualitative parameters (genetic engineering, transsexual surgery), manage the natural "time" of death as an organism in as a whole, and its separate parts (for example, euthanasia, resuscitation, transplantation, gerontology).

For example, the first legal document that took into account the spiritual and moral issues and was aimed at protecting human rights and freedoms against the development of biomedical knowledge and technologies for managing human life processes, was the Nuremberg Code of 1947 [3]. It is known that it was adopted by the International Military Tribunal on the basis of medical research related to experiments on humans, their organs, etc. in Nazi Germany. Moreover, information about the practice of applying biomedical effects on living people has led to the development of research and biomedical technologies around the world. At the same time, the active development of these technologies, as well as the lag in the spiritual, moral and legal regulation of these processes, has given rise to a lot of negative phenomena.

Therefore, in 1957 the World Health Organization (hereinafter – WHO) prepares and adopts a resolution "Protection of the human person and his physical intellectual integrity, taking into account the achievements of biology, medicine, biochemistry." International legal documents, spiritual, moral and professional standards devoted to this issue are beginning to be integrated in various national legal systems, and special legal regimes are being developed to protect and safeguard human rights and freedoms in this area [4].

On April 18, 1979, the US Department of Health, Education, and Welfare established a formal Commission to develop a document that many consider to be the birth of bioethics: Report Belmont "Ethical principles and guidelines for the protection of people involved in the study" [5]. This is the result of a public scandal to which the US Department of Health, Education and Welfare was forced to respond when it became known about an incident in Taskigi, where a kind of "Taskigi experiment" took place (a clinical study conducted in 1932 to 1972). This study examined the natural course of syphilis in a group of black people for thirty years, and despite the availability of effective drugs at the time, the study was continued, including with funding from the US federal budget. This experiment has caused much controversy and led to

changes in the legal protection of patients in clinical trials [6, 7].

The international legal system for the protection of human rights is aimed primarily at creating conditions at the national level to prevent violations of any rights, as well as their restoration. Therefore, the basic principles of international humanitarian law in the field of bioethics should be enshrined in the Basic Law of each state and introduced into medical legislation. In particular, it is necessary to provide for the protection of the human embryo. As, for example, this is done in the Constitution of the Swiss Confederation: "Man is subject to protection against the abuses of reproductive medicine and genetic engineering. The Union issues orders for the treatment of human embryos and hereditary material. He cares for the protection of human dignity, personality and family, especially adheres to the following principles:

a) all types of cloning and interference with the hereditary material of human gametes and embryos are unacceptable;

b) non-human embryonic and hereditary material cannot be introduced into or synthesized with human embryonic material;

c) Medically assisted reproduction procedures may be used only if infertility or the risk of serious illness cannot be eliminated otherwise, but in no way to create certain properties in the child or to conduct research; fertilization of human eggs outside a woman's body is allowed only under the conditions established by law; [8]

d) embryo donation and all types of surrogacy are not allowed;

e) any trade in human embryonic material and embryo derivatives is prohibited.

Trafficking in human organs is prohibited. Man and his environment must be protected from the abuse of genetic engineering. "

Such legislative protection of the human embryo complies with the provisions of Art. 18 of the Convention for the Protection of Human Rights and Dignity of Human Rights in connection with the application of advances in biology and medicine, which states: The creation of human embryos for research purposes is prohibited.

According to Art. 18 of the Additional Protocol to the said Convention, the conduct of research on a pregnant woman, the potential results of which may not directly benefit her health or the health of the embryo, fetus or newborn child, is possible only if the following additional conditions are met:

1) the purpose of research is to contribute to the achievement of results that may be useful for the reproduction of other women or for other embryos, fetuses or children;

2) comparisons on the effectiveness of research on women who are not pregnant are prohibited;

3) research is associated only with minimal risks [9].

However, in the late twentieth century. it becomes clear that, on the one hand, the legal regulation clearly does not keep up with the development of biomedical knowledge and technologies, and the legal coding of relations in this area is clearly overdue; on the other hand, there is an understanding that formal legal regulation is not able to provide all the features, turns, directions and specific practices of biomedical impact on humans and counteract the negative consequences of scientific discoveries.

All this prompted the development of a system of knowledge, forms and regulators, which have primarily a spiritual and moral dimension, and the formation of the concept of bioethics ("Christian Bioethics", "Moral Bioethics", various professional and international ethical systems and codes of conduct).

In a general sense, bioethics is a category of spiritual and moral, has different dimensions: religious, ethical, social, legal, medical, political. This concept was introduced into scientific circulation in the 80's of the twentieth century. Van Rensselaer Potter and is associated primarily with the socio-ethical problems of modern medicine, issues of human rights (both self-determination of their own "life program" and their right to life, moral, intellectual and physical health) [10].

Bioethical norms have been actively introduced in Ukraine since 1991. Such norms include codes, regulations, legislative acts. The main regulatory documents are the Constitution of Ukraine, the Civil Code of Ukraine, the laws of Ukraine "On organ transplantation and other anatomical materials", "On drugs", "On protection of the population from infectious diseases", "On prevention of acquired immunodeficiency syndrome (AIDS) and social protection of the population ", " On psychiatric care ", " On scientific and scientific-technical examination ", as well as " On wildlife ", " On veterinary medicine ", resolutions of the Verkhovna Rada and the Cabinet of Ministers of Ukraine.

The first Ukrainian Congress on Bioethics was held in Kyiv in 2001, at which principles were

adopted in accordance with the requirements of bioethics in the interests of the protection of biological objects. In 2009, NASU adopted the Code of Ethics of the scientist of Ukraine, which formulated ethical principles during experiments on living organisms. The second half of the 20th century made it clear that bioethics must go ahead of any scientific activity. And the control over the observance of the basic principles is entrusted to the committees on ethics and bioethics.

V. THEORETICAL AND PRACTICAL PROBLEMS OF BIOETHICS IN THE CONTEXT OF MODERN CULTURE

The past and the present century have caused a huge number of problems and questions. Many of them are associated with the growing population of the planet, depletion of minerals, clean water, catastrophic deforestation, development of new territories, etc. Crisis phenomena in the environmental, demographic, anthropological spheres have reached catastrophic proportions. The problem of human survival in the current conditions becomes a priority. Awareness of the general nature and the inability to solve problems by the usual means of science, technology and engineering have forced mankind to pay attention to ethics. The development of the whole human society is inconceivable without further scientific and technological progress, which poses a huge number of problems, including those considered by bioethics. Among the problems of bioethics, the problems of transplantology, the question of determining the moment of the beginning and end of human life, and others are quite indicative of the possibilities of scientific study and substantiation. [11, 12]. Turning to bioethical issues, we not only grasp the new heights of scientific knowledge, philosophy, the human spirit in general, but also identify the deepest "abysses where modern humanity has entered and where it seeks solutions." The idea of the need for true humanization of scientific knowledge penetrates today into all branches of science, and in bioethics it should become one of its essential foundations [14]. The focus of Western and American options for defining bioethics is medical ethics (and partly environmental). Its conceptual foundations are four principles and three rules, most closely related to medical ethics.

The first principle – "first of all – do no harm." Its wording raises the question of what "harm" means in this context. And here are a few options:

- 1) damage caused by failure to provide assistance to those who need it – inaction;
- 2) damage caused by irresponsibility or malicious intent;
- 3) damage caused by unqualified or incorrect, reckless actions of the doctor;
- 4) damage caused by necessity.

A detailed analysis of these options shows that the essence of the principle is that the doctor is obliged to exclude harm to the patient by his actions or inaction, or to minimize it. The second principle of "do good" can be seen as a direct continuation and extension of the first. He orients the doctor to active actions not only to avoid harm, but also to eliminate or correct it. In the extreme case, this principle calls for self-sacrifice and altruism. The third principle not only fixes the recognition of the patient's autonomy, but focuses on respect for him. This means that even if the patient chooses a method of treatment that is not recognized as the best by the doctor, the latter is obliged to accept this choice and make it in the best way for the patient. The fourth principle of bioethics is the principle of justice. It is one of the most difficult to understand. In bioethics, it can be formulated something like this: everyone should get what belongs to him. However, in conditions of limited access to some necessary resource (finances, equipment, medicines, qualified specialists, etc.) there is a problem of its fair distribution. Modern science and culture are unable to understand that the separation from human subjectivity, its neglect for the sake of "objectivity" in the study of man makes the acquired knowledge unscientific. As a result, some elements of irrational, philosophical, value knowledge penetrate into scientific knowledge.

VI. ETHICAL AND LEGAL ASPECTS OF EXPERIMENTAL PRACTICES

In today's world, the requirements for biomedical research are clearly defined. The objectives of clinical and biomedical trials performed at biological sites must be substantiated and approved by independent ethics committees [15]. It is impossible to completely remove the risk in such studies, but it is necessary to justify and prevent it, so that, for example, a person does not fall victim to unprepared experiments, the results of which can cause unexpected harmful consequences.

Adherence to all requirements is guaranteed by legal norms that will save a person from new methods of treatment [16]. For a long time, biomedical research was governed only by the moral attitudes of experimenters, but as numerous examples show, society demanded the creation of a new legal document that would regulate the conduct of experiments with human participation. The first such document was the Nuremberg Code (1947). The Code emphasized the indispensability of obtaining the subject's voluntary consent to participate in research, as well as defined the basic rights and responsibilities of the parties [17]. In 1964, in Helsinki, the 18th Congress of the General Assembly of the World Medical Association adopted a declaration "Recommendations for physicians to conduct biomedical research with human participation as the object of study", which is now the main document regulating human rights in biomedical research [18]. The first application of the declaration took place in 1975 after the discovery of numerous violations of ethical principles, so the requirement of prior approval of the protocol by an independent ethics committee was applied [18].

I would like to highlight some important, in our opinion, areas of bioethical and medical law that concern the world community. Note that the legal history of bioethics began after the Nuremberg tribunal, when the truth about the actions of Nazi doctors became known throughout the world, and human experiments were first discussed and condemned. It then became known that Nazi doctors had killed 70,000 people: the physically handicapped, the mentally ill, the Gypsies and the marginalized. They developed an effective euthanasia program. Some doctors, despite the oath of Hippocrates, conducted experiments on prisoners of war and people who were deported from other countries. At the Nuremberg Trials, the world for the first time questioned the integrity of doctors and medical ethics. There have also been cases of doctors experimenting in Japan during World War II, and later in the United States, a country that revealed information about the actions of Nazi doctors to the world and was proud of its respect for human rights. Two of them particularly impressed the public:

1. In 1963, in the city of Brooklyn, in one of the hospitals for victims of chronic diseases as a result of experiments, without the consent of patients, active cancer cells were introduced.

2. In 1965-1971, a study on hepatitis B virus infection was conducted at Willoughbrook Hospital, New York. In an experiment, hepatitis B virus was administered to children with physical disabilities who were in that hospital.

The development of general rules for clinical trials was also prompted by the 1959-1961 thalidomide catastrophe. From 1956 to 1962, more than 10,000 children worldwide were born with developmental defects due to thalidomide [19]. Experiments on mustard gas infection were conducted in other concentration camps. He was forced to inhale or given in a liquid state and the effects of his exposure were observed. [20]. An experiment was also performed on women to regenerate bones, muscles and nerves. The blade was used to make cuts on the legs, and then bacteria and foreign objects were injected to infect the blood. Then the infected cuts were treated by various means, checking their effect. Gangrene often occurred, after which some women were treated and others were left untreated [11]. In other experiments, cheap and rapid castration was tested on convicts in concentration camps; mass infection of people with typhus was carried out; the effect of phosphorus compounds on the human body was tested [21]. Such data, confirmed by the relevant documents, not only shocked the world community, but also made us think about the problems of protection of the rights, dignity and health of the subjects [17]. Two examples that strike with unfounded inhumanity towards people have attracted special attention. In the first case, it was a study conducted at a boarding school for retarded children in Willowbrook. To study the etiology of the disease, children were deliberately infected with hepatitis B. Otherwise, doctors injected patients with live cancer cells in a New York hospital [22]. Unfortunately, this is by no means a complete list of biomedical research conducted on humans, but it makes us think about the value of human life. The other side of the experiments is the attitude of the subjects and the goals they pursue, agreeing to act as subjects. Every year, global pharmaceutical companies recruit volunteers to test new drugs and vaccines. For seriously ill people, this is a chance to be cured with the help of goods that have not entered the markets. After all, no one can say exactly how much the drug will cost, in the case of passing all stages of clinical trials. Another category of volunteers are perfectly healthy people who want to profit from experiments [15]. Citizens of

underdeveloped countries, including many Hindus and Africans, often agree to this risk. Sometimes, to save on such experiments, patients are not informed of any trials. And such "confidential" experiments do not always end successfully. [20]. A similar experiment was conducted in Nigeria. In 1996, one of the pharmaceutical companies tested the antibiotic on children with meningococcal syndrome. The result was 11 deaths and hundreds of injuries. Another experiment was conducted by a Beijing clinic together with an American company. In 2003, a drug was tested to fight HIV. The control group, which included HIV-infected individuals, received placebo injections. Experiments have shown that HIV / AIDS cannot be cured with placebo, as most of the control group died [24, 25]. It is very convenient to conduct clinical trials in India, Africa, China and other densely populated countries due to the unlimited number of subjects, low income and ignorance of citizens.

Before testing new pharmaceuticals, devices and equipment, as well as new treatments in humans, it is necessary to ensure their biological safety by conducting a series of preclinical and biomedical studies. Most often, such in vivo experiments are performed with the participation of laboratory animals, as alternative models (without the use of animals) can not completely replicate the complex human body. Experiments on animals allow not only to better understand the mechanisms of individual life processes, but also to improve methods of prevention, diagnosis and treatment of diseases. It was experiments on animals that made it possible to find a cure for zoonotic diseases and thus save endangered species. However, the use of animals as objects of study raises questions of ethics and morality. Such an opportunity should not give companies the right to abuse and create a field for conflict [26]. Experiments involving animals must meet the goals and objectives set by the experimenter. Due to the emergence of bioethics, there is an ethical examination to verify compliance with all standards when using laboratory animals in research. Humane treatment of animals allows to increase the formation of high moral principles in the experimenter.

Modern ethics of medical research – bioethics.

Bioethics was formed as an intellectual activity associated with disputes over the interpretation of certain social practices in the field of biomedicine and biological research. If at first the issues of moral justification of certain practices were discussed

(abortion practices, new reproductive technologies, euthanasia practices), then later specific practical cases in medicine, pharmacology and biology emerged with the emergence of new technologies. Bioethics described the behavior of subjects who found themselves in situations of choice of behavior, gradually taking on the role of analysis of real relations in a particular field of activity and at the same time forming the basis for regulating human activity [27, 28].

The development of bioethics is associated with the process of transformation of ethics in general and medical ethics in particular. This phenomenon is associated with increased attention to the problems of morality and law in the application of new technologies and drugs on biological objects [11, 13]. In addition, the development of a new discipline is due to technological re-equipment of modern medicine, changes in the clinical and diagnostic field, the development of genetic engineering, the emergence of equipment for artificial support of the patient's life. All this drew public attention to the moral problems that arise between the patient and the health worker [29, 30]. At the heart of medical activities are not only data on the results of treatment, but also the results of experiments and clinical trials [31].

Today, the development of biomedical technologies requires the creation of an ethical and legislative concept of clinical practice and research in accordance with the current development of medical-biological and chemical-pharmaceutical science, as well as the requirements of the psycho-social factor [32, 33].

There is no country that does not recognize the obligation to protect human rights in all spheres of public life and, above all, in research, when a person becomes particularly vulnerable. To date, there are developed and tested in practice the rules of such research, as well as mechanisms to monitor compliance with these standards. The main principle in conducting clinical trials is to protect the rights and health of subjects. Such a mechanism is the ethical control of any clinical research, which means not only the testing of new drugs, but also the testing of modern medical equipment, surgery, research in the field of genetics, psychology and others. Animal studies are also appropriately monitored and regulated. Conducting biomedical research is considered unfair, immoral and even criminal if the law is not followed. The medical community has reached the unanimous opinion that

any activity of a medical worker in relation to biological objects must comply with moral standards [31, 34].

When conducting clinical / pre-clinical studies with human participation, in addition to ethical norms, legal norms that regulate the relationship between the parties in the legal field should be followed. According to the regulations, the doctor or experimenter has neither the moral nor the professional right to expose the subject to increased risk and to use methods that may harm the patient. The research specialist should explain the methods, goals, side effects and possible risks of such studies, focusing on the characteristics of each person [35, 36]. The ethical basis of the experiment is the doctrine of patient awareness under the condition of any medical intervention and confidentiality.

VII. PROSPECTS OF BIOETHICS AND ETHICAL CULTURE OF RESEARCH

In the history of bioethics there is a tendency to neglect the use of the concept of research bioethics. Preference is given to the use of a more neutral concept, such as biomedical ethics, and in the field of human research – research ethics. In both cases, the term is rarely used not only because it includes the question of double interpretation, but also because bioethics refers more to the representative of society. A more specialized bioethics that would transform morality into metaethics (with a certain analytical and philosophical context) and a difficult dialogue between experts or non-experts into an interdisciplinary dialogue are a more flexible and manageable form of ethics. This trend toward a more specialized approach is common in the modern bioethics literature. Technical and expert knowledge occupy a privileged position today, and the activities of ethics committees are increasingly engaged in expert people, thus emphasizing the role of a representative of society [37, 38].

The term "bioethics" is a kind of distant ideal aimed at changing the moral personality. That is why we could talk about biomorality. This would make it possible to speak of the high ideals of bioethics and its close connection with the ordinary citizen, who receives the advantages and disadvantages of research and medical activities.

Research ethics is guided by international and local rules governing the procedures adopted to protect the integrity and exercise the rights of research subjects. All this is aimed at training various participants in the research process in order

to involve them in the analysis of ethical, legal and methodological components of a particular protocol. Perhaps the most important part is the rationing of the process, the coordination of different interests, the reconciliation of conflicts in order to achieve coherence, both fair and effective. The most difficult thing is to ensure compliance with ethical principles of research management, transparent institutional procedures that satisfy all parties [16, 24].

The main task of bioethics in the field of research with humans is to create a space of tolerance that would allow an open exchange of different points of view. This tolerance is an area of active dialogue, convergence of views that can be common, and especially lead to procedures that allow joint management in regulatory activities [39, 40].

Ethics of research means not only mastering virtuous habits that would lead to positive behavior when working with research subjects, but also the ability to establish procedures and rules that allow the application of international standards. The result of such a culture could be the creation of a so-called empirical moral state – a normal state. It would be a set of regulatory institutions, institutes for evaluation and monitoring, as well as standards that in one form or another would reflect the spirit of international guidelines for research ethics.

All this requires strong political support of democratic political systems, constitutional authorities, as well as appropriate social and economic development that will ensure a certain well-being and quality of life of the people of the country [24, 37].

VIII. CONCLUSIONS

As a result, the literature was reviewed and the main causes and consequences of the application of bioethical principles in human practice, namely in biomedical research. The paper proves that the key task of bioethics and the highest value of society is the preservation of human life, its dignity and autonomy. However, the international legal regulation of bioethical problems is only at the stage of formation and formation. It is characterized, on the one hand, by the unity of intentions of the world to regulate these issues based on the concept of human dignity and generally accepted international legal standards in the field of human rights, and on the other hand, the existence of different models of

bioethics, different approaches to interpreting a number of evaluation concepts.

The key task of bioethics is to protect the rights and freedoms of biological objects in biomedical and scientific research. To this end, appropriate legal documents have been created that regulate the treatment of living organisms during appropriate experiments to prevent any bullying and killing for the sake of discovery. To achieve such standards, humanity had to go through the Nuremberg tribunal, the tragedy in Taskiga, and the bullying in the hospitals of Brooklyn and Wilbrook in the 20th century. But having passed this difficult path, the world community has reached a point of no return – the creation of the science of bioethics and documents governing the relevant actions. At the national level, it is also necessary to criminalize violations of international standards for biomedical research using organisms, strengthen other types of responsibilities and create a special system of government agencies responsible for policies for their use for biomedical purposes and control in this area. Therefore, we draw the following conclusions:

1. Currently, progress dictates its methods of testing and implementation of innovative products, but the leading empirical way to confirm the scientific significance of the studied material is the experiment.

2. The prevailing opinion among researchers is that conducting experiments is necessary for the further development and implementation of medical developments, but its stages can be carried out only under strict control and observance of ethical norms.

3. The issues of significance and humanity in conducting experiments on humans, considered in this article, remain relevant today.

4. For many decades, the main object of biomedical research are animals, and all sorts of moral and legal documents regulate this process.

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БІОЕТИКА В КОНТЕКСТІ СОЦІАЛЬНО-ЕКОНОМІЧНОГО, СОЦІАЛЬНО-ПОЛІТИЧНОГО ТА КУЛЬТУРНОГО РОЗВИТКУ СУСПІЛЬСТВА

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Реферат – Біоетика – не лише новий напрямок в науці, але й інша сфера філософського пізнання життя та його збереження на Землі. В роботі розглянуто проблеми етико-правового регулювання сучасних біомедичних досліджень, де одним із методів вивчення та опису об'єктів навколишнього середовища є експеримент. Він є ключовим інструментом практики, без якої неможлива теорія. Враховуючи темпи розвитку сучасної науки та загалом світу, актуальною є тема вивчення принципів регулювання біомедичних досліджень та їх удосконалення. У статті також висвітлено основні принципи використання людей та тварин у біомедичних дослідженнях. Пояснено чому так важливо посилити гуманізацію цього процесу. Висновки: дуже важливо запобігати жорстокому поводженню з будь-якими біологічними об'єктами в контексті вирішення біоетичних та правових проблем, пов'язаних із реалізацією принципу гуманізму та захистом прав живих організмів. Сучасна наука та практика доклінічних та клінічних випробувань повинні бути залучені до цієї проблеми з метою вдосконалення та універсалізації процесу медико-біологічних досліджень *in vitro*. Мета статті – вивчити основні міжнародно-правові принципи використання організмів у біомедичних експериментах, а також визначити основні проблеми з цього питання та окреслити шляхи їх вирішення. Оглянути сучасний стан етико-правового регулювання, принципів та правил проведення експериментальних медико-біологічних досліджень. На сьогоднішній день міжнародне співтовариство прийняло достатньо правових актів, що регулюють належне проведення біомедичних доклінічних та клінічних досліджень з біологічними об'єктами, в тому числі спеціально вивчених для таких досліджень організмів (в лабораторії). Останнім часом як у національному законодавстві європейських країн, так і в міжнародному законодавстві спостерігаються тенденції посилення їх захисту у галузі біомедичних досліджень. В статті приведено приклади знуцання, і як наслідок прямого порушення основних принципів біоетики – поваги до автономності та гідності людини. Доведено, що основна задача біоетики – збереження життя та здоров'я кожного організму. Обов'язковим є як на міжнародному, так і на національному рівнях прийняття програм розвитку та підтримки наукового вивчення впровадження біосистем *in vitro* у практику досліджень. На національному рівні необхідно криміналізувати порушення міжнародних стандартів проведення біомедичних досліджень з використанням організмів, посилити інші види відповідальності та створити спеціальну систему державних органів, відповідальних за політику їх використання у біомедичних цілях та здійснення контролю в цій області.

Ключові слова: біоетика, медична етика, мораль, регулювання, біомедичні дослідження.

БИОЭТИКА В КОНТЕКСТЕ СОЦИАЛЬНО-ЭКОНОМИЧЕСКОГО, СОЦИАЛЬНО-ПОЛИТИЧЕСКОГО И КУЛЬТУРНОГО РАЗВИТИЯ ОБЩЕСТВА

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Реферат – Биоэтика – не только новое направление в науке, но и другая сфера философского познания жизни и его сохранения на Земле. В работе рассмотрены проблемы этико-правового регулирования современных биомедицинских исследований, где одним из методов изучения и описания объектов окружающей среды является эксперимент. Он является ключевым инструментом практики, без которой невозможна теория. Учитывая темпы развития современной науки и в целом мира, актуальной является тема изучения принципов регулирования биомедицинских исследований и их усовершенствованию. В статье также отражены основные принципы использования людей и животных в биомедицинских исследованиях. Объяснено почему так важно усилить гуманизацию этого процесса. Выводы: очень важно предотвращать жестокое обращение с любыми биологическими объектами в контексте решения биоэтических и правовых проблем, связанных с реализацией принципа гуманизма и защитой прав живых организмов. Современная наука и практика доклинических и клинических испытаний должны быть привлечены к этой проблеме с целью совершенствования и универсализации процесса медико-биологических исследований *in vitro*. Цель статьи – изучить основные международно-правовые принципы использования организмов в биомедицинских экспериментах, а также определить основные проблемы по этому вопросу и наметить пути их решения. Осмотреть современное состояние этико-правового регулирования, принципов и правил проведения экспериментальных медико-биологических исследований. На сегодняшний день международное сообщество приняло достаточно правовых актов, регулирующих надлежащее проведение биомедицинских доклинических и клинических исследований с биологическими объектами, в том числе специально выращенных для таких исследований организмов (в лаборатории). В последнее время как в национальном законодательстве европейских стран, так и в международном законодательстве наблюдаются тенденции усиления их защиты в области биомедицинских исследований. В статье приведены примеры издевательства, и как следствие прямого нарушения основных принципов биоэтики – уважения к автономности и достоинства человека. Доказано, что основная задача биоэтики – сохранение жизни и здоровья каждого организма. Обязательным является как на международном, так и на национальном уровнях принятия программ развития и поддержки научного изучения внедрения биосистем *in vitro* в практику исследований. На национальном уровне необходимо криминализировать нарушение международных стандартов проведения биомедицинских исследований с использованием организмов, усилить другие виды ответственности и создать специальную систему государственных органов, ответственных за политику их использования в биомедицинских целях и осуществления контроля в этой области.

Ключевые слова: биоэтика, медицинская этика, мораль, регулирование, биомедицинские исследования.