

# CRIMINAL AND LEGAL RESPONSES TO VIOLATIONS OF BIOETHICAL STANDARDS IN MEDICINE: CHALLENGES FOR LEGAL POLICY IN THE 21ST CENTURY

## LITERATURE REVIEW

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### INTRODUCTION

The contemporary stage of human development is characterized by rapid advances in biomedicine and the widespread application of modern medical technologies, as well as by the expansion of medical interventions affecting the human body and mind. Progress in genetics, transplantation medicine, reproductive medicine, pharmaceutical clinical trials, digital devices, and artificial intelligence in healthcare has transformed long-established views regarding the extent to which human intervention may exert significant or negligible influence on human life and health. In this context, bioethical standards acquire particular importance as systems of values, legal norms, and professional guidelines designed to ensure human dignity, autonomy, and individual rights in the field of healthcare.

This issue is especially relevant because violations of bioethical standards in medical practice are increasingly no longer confined to the prerogative of specialists or other trained professionals, but are acquiring the characteristics of socially dangerous conduct that requires a response from the criminal justice system. Illegal medical interventions, violations of the principle of informed consent, abuses in clinical trials, unlawful activities in the field of organ and tissue transplantation, and manipulations involving embryonic or reproductive material pose a serious threat to human life and health, undermine trust in the healthcare system, and call into question existing mechanisms of legal protection.

Moreover, this problem is of particular importance for the structuring of modern legal theory based on the protection of human rights and compliance with international bioethical standards. Criminal law plays the role of an ultimate, yet the most severe, form of state response, and its application must be grounded in the principles of legality, proportionality, and legal certainty. At the same time, the absence of a clear normative distinction between bioethical violations that entail disciplinary or civil liability and those constituting legitimate criminal offenses

leads to ambiguity in law-enforcement practice and creates the risk of excessive criminalization of medical practice.

The relevance of this research is further reinforced by the impact of globalization processes and the integration of national legal systems into the European and international legal space. Existing international human rights and bioethics instruments provide broader normative frameworks; however, their incorporation into national criminal legislation is often fragmented and inconsistent. This necessitates a reconsideration of the role of criminal-law instruments in ensuring compliance with bioethical standards and the identification of the most appropriate model of criminal-law response to violations.

In light of the issues outlined above, there is an urgent need to conduct research aimed at developing and revising criminal-law responses to violations of bioethical standards in medicine in order to shape a balanced legal policy for the twenty-first century. Such research contributes to a clearer understanding of the limits of criminalization in the medical field within legal theory, to the development of criminal law, and to the effective protection of human rights and freedoms in the context of contemporary biomedical advancement.

**Objective of the review:** to carry out a comprehensive scientific and legal analysis to assess criminal-law responses to violations of bioethical standards in medical practice, to address challenges of legal policy in the contemporary context of the twenty-first century, and to formulate theoretically grounded and practically significant recommendations aimed at improving criminal legislation and law-enforcement practice in this field.

To achieve this purpose, the objectives of the study include:

- analyzing the concept and substance of bioethical standards in medicine and determining their place within systems of legal regulation;
- describing bioethical norms in relation to norms in the fields of medicine, criminal law, medical law, and international law;

- examining the evolution of legal doctrines and principles governing criminal and civil policy in the protection of bioethical values – namely life, health, dignity, and personal autonomy – within national legislation and the legal systems of other jurisdictions;
- investigating the elements and characteristics of existing criminal offenses that may give rise to liability for violations of bioethical values in medical practice, as well as assessing their conceptual, normative, and practical deficiencies;
- determining the role of criminal-law policy in shaping processes of criminalization and decriminalization of violations of bioethical values in accordance with the principles of subsidiarity of criminal law, proportionality of criminal-law intervention, and legal certainty;
- substantiating proposals for improving criminal legislation and law-enforcement practice in light of international bioethical norms and recent developments in medical science;
- formulating scholarly conclusions and recommendations aimed at enhancing the effectiveness of criminal-law protection of bioethical values and establishing a reasoned and balanced legal policy in the field of medical science.

## METHODOLOGY

This study is based on general scientific, special legal, and interdisciplinary models of inquiry, the application of which is determined by its complexity, given that the criminal-law response to bioethical violations in the field of medical practice is inherently diverse. One of the general scientific methods employed in the research is the dialectical method, which makes it possible to examine bioethical standards and the mechanisms of their criminal-law protection in their development, interconnection, and interaction with social processes, scientific and technological progress, and transformations in legal policy.

The systemic-structural method is used to determine the place of bioethical standards within the system of legal regulation and to analyze the interaction between norms belonging to criminal law, medical law, and international law. With regard to the application of methods across different branches of knowledge, the formal-logical method is employed to analyze bioethics, criminal liability, and medical practice through the categories, concepts, and definitions used in the study, as well as to ensure the internal consistency of scientific conclusions. Analytical and synthetic methods make it possible to decompose complex legal phenomena into individual elements and, at the same time, to form an integrated understanding of the criminal-law response to violations of bioethical standards.

Special legal methods include the formal-legal method, which is applied to the examination of normative provisions of criminal law concerning liability for violations of bioethical standards, as well as to the identification of gaps, conflicts, and inconsistencies in legal regulation. In analyzing foreign experience in the criminal-law protection of bioethical values, the comparative legal method is employed to assess the possibility of adapting such experience to the national legal system. Within the framework of applied research on the implementation and impact of criminal-law instruments on the actual behavior of subjects engaged in medical practice, the socio-legal method is used.

Within the scope of scientific research, it is appropriate to state that the search and selection of scientific sources for this article was carried out in the time frame of 2000–2025, with priority given to publications from 2020–2025, due to the need to take into account current trends in the development of biomedicine, bioethics, and criminal law regulation of medical activities. The analysis included both fundamental doctrinal works and the latest research reflecting current approaches to the criminalization of violations of bioethical standards. In addition, the source base was formed by processing scientific publications, monographs, commentaries, international legal acts, and judicial practice presented in scientometric and academic databases, in particular Scopus, Web of Science, Google Scholar, Springer Link, Oxford Academic, as well as in the official resources of international organizations and intergovernmental institutions. A separate group of sources consists of international normative acts in the field of bioethics and human rights, documents of international organizations, and the practice of international judicial institutions. At the same time, the criteria for selecting sources were: thematic relevance to the issues of bioethics and criminal law response in the field of medicine; scientific peer review of publications; the authority of publishers or international institutions; the existence of established scientific citations; the normative force of legal acts; interdisciplinary significance for criminal and medical law.

Given its interdisciplinary nature, the study integrates approaches and findings from criminal law, medical law, bioethics, and legal policy, thereby ensuring a comprehensive analysis and facilitating the development of well-founded conclusions regarding the optimization of criminal-law responses to bioethical violations in medicine. At the same time, the combined use of these methods contributes to the achievement of the research objectives and provides scientifically grounded recommendations for improving criminal-law policy in the healthcare context.

## ANALYSIS OF LITERARY DATA

The issue of the criminal-law response to violations of bioethical values in medicine is inherently transdisciplinary, situated at the intersection of criminal law, medical law, bioethics, human rights, and criminal justice. Contemporary literature reviews indicate that this area is unevenly explored: certain aspects of bioethics and medical law are well-established, with the exception of some disciplinary elements that remain under-researched, while the criminal-law aspects of bioethical violations concerning human rights are largely addressed in a fragmented manner. Research in this field can be organized into several distinct strands.

The first strand comprises works related to the general theory of bioethics and medical law, which articulate the fundamental principles of legal and ethical regulation of medical practice. J. Herring [1] outlines principles such as patient autonomy, informed consent, dignity, bodily integrity, and liability for breaches of medical practice standards. A similar approach is reflected in the work of Fremgen, F. Bonnie [2], where medical liability is examined from the perspective of professional ethical standards, risk reduction, and patient safety. These studies acknowledge criminal-law mechanisms as one of the instruments of response, although they do not provide a detailed analysis of the

criteria for criminalizing bioethical violations. The philosophical and legal relationship between human rights and bioethics is highlighted in the works of Maria do Céu Patrão Neves [3] and in collective studies by F. Stokes & R. Iskander [4]. These sources emphasize that, while bioethical standards are closely intertwined with the human rights paradigm, mechanisms for their enforcement through criminal law remain disputed.

The second strand involves more formal theoretical and doctrinal analyses of criminal law, which indirectly inform the understanding of the limits of criminalization in medicine. For example, in the work of A. Ashworth [5], the principles of criminalization, proportionality, and *ultima ratio* are examined, directly relevant for evaluating the boundaries of professional medical intervention under criminal law. In contrast, comparative analyses such as those by M. Gałazka [6] and M. Esposito et al. [7] explore the paths of two distinct legal systems toward criminal liability in medicine, particularly regarding negligence, unlawful medical procedures, and violations of patients' procedural guarantees. In these studies, bioethical standards are not treated as a separate object of criminal-law protection but are considered through the traditional categories of harm to life and health.

The third strand consists of research on international bioethical and human rights regulation. International instruments represent significant factors in scholarly debates, including the Council of Europe Convention on Human Rights and Biomedicine [8], the UNESCO Universal Declaration on Bioethics and Human Rights [9], and the Charter of Fundamental Rights of the European Union (EU). Doctrinal interpretations are provided in the works of R. Andorno and M. Neves, which address the content and significance of the Oviedo Convention, as well as in commentaries on the EU Charter edited by S. Peers et al. [10], which articulate standards on respect for human dignity, the preservation of bodily integrity, and the prohibition of abuses in biomedical practices. While these sources establish a normative basis for bioethical imperatives, the issue of criminal-law sanctions generally remains at the level of general state obligations.

An additional body of literature concerns the practice of the European Court of Human Rights (ECtHR), which significantly influences the state's response to violations in healthcare systems. Cases such as *Calvelli and Ciglio v. Italy* and *Šilih v. Slovenia* are particularly noteworthy; the Court established the concept of positive state obligations to properly investigate cases of death or serious harm in healthcare contexts where a legal issue arises. As emphasized by L. Timofieieva [11], the procedural aspect of protecting the right to life and health is of particular importance, and the ECtHR's criminal-law approaches are accordingly considered. However, scholarly reviews of this case law focus more on procedural aspects than on systematic considerations, with relatively less attention to the criminalization of bioethical violations.

In domestic and regional scholarship, the relationship between bioethics and criminal law constitutes another distinct research direction. Y. Trynova [12] provides a detailed analysis of the application of bioethical principles in Ukrainian criminal law, emphasizing key elements such as informed consent, dignity, and acceptable medical procedures. Y. Zabuga [13] examines criminal liability in practice when medical guarantees are violated under the pretext of the right to free healthcare. O. Harasymiv [14] in-

vestigates the legal implications of Ukraine's potential ratification of the Oviedo Convention, including its impact on national legislation governing medical and biological interventions. In these studies, a comprehensive criminal-law response to violations of bioethical standards is notably absent. Additionally, more general legal literature, such as the article by O. Sitarz et al. [15], raises questions about the limitations and possibilities of criminalizing bioethical violations in the context of human rights.

Additionally, contemporary scholarship demonstrates an increasing focus on the criminal-law dimensions of violations of bioethical standards in the pharmaceutical and medical fields, particularly in relation to professional responsibility and the protection of patients' rights. Thus, O.H. Aleksieiev [16], examining the national pharmaceutical sector, substantiates the need for a criminal-law response to systemic abuses in the circulation of medicinal products, emphasizing the interconnection between the theoretical foundations of criminalization and the practical challenges of law enforcement. The criminological dimension of confidentiality protection in healthcare is explored in the work of A. Baida [17], who identifies the persistence of negative institutional practices (authoritarianism in doctor-patient relations, the declarative nature of legal norms, and low levels of professional accountability) and underscores that the social harmfulness, prevalence, and latency of unlawful disclosure of medical secrecy are key factors justifying the establishment of criminal liability. A distinct strand of research addresses informed consent as a core bioethical and legal safeguard: P. Daniluk [18] analyzes criminal liability for conducting clinical trials without informed consent, while G.P. Kovane et al. [19] & D.-H. Tereshkevych et al. [20] focus on the ethical and legal requirements governing its content and procedure; issues of risk communication and the potential legal consequences of its deficiencies in antimicrobial research are comprehensively synthesized in the scoping review by Y. Shou et al. [21]. In the context of the digitalization of medicine, T. van Rijssel et al. [22] draw attention to the "soft" impacts of technology in decentralized clinical trials, which complicate the assurance of genuinely informed consent and potentially expand the scope of criminal-law risks. Finally, the comparative analysis by Y. Tkach [23] concerning criminal liability for violations of legally established procedures for the transplantation of human anatomical materials reveals the fragmented nature of national regulation when compared with foreign experience, thereby reinforcing the conclusion that a coherent and integrated model of criminal-law protection of bioethical values in medicine remains absent.

In this context, it is also pertinent to highlight the specific literature on criminal liability in medicine and the ethical aspects of clinical research, which encompasses several major areas: criminal liability of healthcare professionals, ethical and legal aspects of informed consent, and international and comparative legal approaches.

First, criminal liability in medical practice (studies in this category examine the grounds and limits of criminal responsibility of medical professionals for improper performance of professional duties, medical negligence, and related issues). For example, S. Ost analyses the need for clearer legal regulation of cases of involuntary manslaughter in medicine and proposes

enhancements to the criminal framework [24]; P. Thahir and T. Tongat explore patient protection and professional liability of medical practitioners in the context of medical crimes [25]; V. Artiukhova compares the European experience of criminal liability for unlawful medical activities in Germany, France, Italy, and Spain [26]; V. Kononenko examine issues related to holding medical professionals accountable under disciplinary and criminal law in Ukraine [27]; N. Kolos conducts a comparative legal study of criminal liability for improper professional conduct in Ukraine and other countries, taking into account the case law of the ECtHR [28]; A. Mirza et al. consider criminal liability for medical negligence and its legal consequences [29]; R. Kulkarni et al. analyze the legal implications of surgical errors and propose an analytical approach to judicial practice [30].

Second, ethical and legal aspects of informed consent (this category focuses on informed consent in clinical research, issues of risk communication, and legal safeguards). For example, van Rijssel et al. address the ethical challenges of decentralized clinical trials and the impact of technology on the informed consent process [22]; A. Sandu examines ethical and legal aspects of informed consent in the context of international human rights law [31]; M. Plaiasu and C. Nanu assess the level of physicians' legal knowledge regarding informed consent and patient confidentiality [32]; J. Putri and A. Jamaludin explore the legal aspects of obtaining informed consent in emergency medical care [33]; C. Pisarenco and M. Manea analyze errors and risks associated with the application of informed consent in clinical practice [34]; M. Bichia and I. Gagua investigate the historical foundations of informed consent and contemporary challenges in practice [35]; I. Risdawati considers the legal aspects of implementing an informed consent system in medical practice [36]; Wang Leifan et al. evaluate the role of bioethics in Chinese biosafety legislation and issues related to informed consent [37]; S. Martin et al. conduct a comparative ethical analysis of Egyptian legislation concerning clinical research [38], among others.

Most of these studies are theoretical and non-discursive and do not provide an additional model of criminal-law policy in this field. Based on this literature analysis, it can be concluded that, while significant progress has been made in medical law, bioethics, human rights, and the general theory of criminalization, an integrated analysis of criminal-law responses to violations of bioethical standards as an autonomous domain remains limited. This underscores the need for a comprehensive approach that combines criminal-law doctrine, international bioethical standards, and law-enforcement practice.

### ***Bioethical standards as an object of criminal law protection: conceptual and legal foundations and the European dimension***

A theoretical understanding of the nature of bioethical standards, their normative status, and their role within protective systems in the fight against crime is essential for the development of criminal-law mechanisms addressing violations of bioethical standards. In the European legal context, bioethics has gradually evolved from an ethical doctrine into a multifaceted normative system that influences the content of criminal law, human rights law, and state legal policy. Consequently, at the

outset of this study, it is necessary to determine under what circumstances bioethical standards acquire criminal-law significance, and when and how they may serve as either an independent or derivative object of protection under criminal law.

In contemporary scholarship, bioethical standards are understood as a system of principles and norms regulating the permissible boundaries of human life, health, and physical and mental integrity in the context of biomedical development. Principles such as respect for autonomy, beneficence, non-maleficence, and justice, as recognized in foundational bioethics works [7], remain the classical core principles of bioethics.

At the European law level, bioethical standards became normative with the adoption of the 1997 Convention on Human Rights and Biomedicine (Oviedo Convention), which explicitly links medical progress with the protection of human dignity and rights [24]. In this scenario, bioethical standards assume legally tangible requirements, and their violation not only creates potential civil and disciplinary liability but also carries the risk of criminal liability. Criminal law doctrine defines the legal object as social relations, which, in turn, constitute the subject matter of the law. In the case of violations of bioethical standards, these social relations are those that guarantee the protection of fundamental human rights in healthcare, namely the rights to life, physical and mental integrity, human dignity, and autonomy of will [5].

Bioethics and criminal law interact in a subtle and complex manner. On the one hand, criminal law cannot and should not extend beyond the scope of bioethical norms, as doing so could result in the over-criminalization of medical practice and the generalization of bioethical principles. On the other hand, neglecting the bioethical dimension of socially dangerous acts diminishes the effectiveness of criminal law in the context of scientific progress for the protection of individuals [1].

In practice, the ECtHR consistently emphasizes that states have positive obligations to protect individuals' health and life in medical contexts, including the establishment of appropriate criminal-law instruments in cases of gross violations [39]. Thus, bioethical standards are indirectly aligned with criminal law through the positive obligations of states, as reflected in Articles 2 and 8 of the European Convention on Human Rights (ECHR). Within EU law, bioethical norms serve as a critical tool for shaping legal policy, particularly in areas such as clinical trials, protection of personal medical data, and the use of biomedical technologies. The Charter of Fundamental Rights of the European Union explicitly prohibits eugenic practices and the commercialization of the human body, which directly relates to the criminalization of relevant acts.

To systematize the normative influence of bioethical standards on criminal law, it is recommended to summarize the key stages of their legal codification (Table 1).

Level	Normative sources	Criminal-law significance
International	Oviedo Convention, UNESCO documents	Establishment of minimum standards for criminalization
European	ECHR, ECtHR case law, EU Charter	Positive obligations of the state

This table illustrates the multi-level nature of bioethical standards as a legal object for protection under criminal law. It is therefore important to note that bioethical standards in the contemporary European legal space are not merely the result of ethically justified prescriptions; they effectively acquire normative roles within criminal-law policy. They act as intermediaries in the content of protection of fundamental human rights under criminal law in the medical context, while also serving as an assessment of the social danger posed by specific medical interventions. This generates a theoretical foundation for the further study of specific forms of violations of bioethical standards and mechanisms of criminal-law counteraction, particularly in the context of legal policy in the twenty-first century.

### ***Criminal-law features of violations of bioethical standards in key areas of biomedicine: normative legal aspects – a comparative law perspective***

Violations of bioethical norms in medicine are not abstract; they occur in specific medical and research activities that pose increased risks to life, health, and human dignity. It is particularly in clinical trials of certain medical products, organ and tissue transplantation, and the implementation of assisted reproductive technologies that bioethical standards most frequently transform into criminal-law constraints. The aim of this section is to examine these aspects within the framework of criminal law and legal policy, taking into account EU standards, the case law of the ECtHR, and international bioethical conventions.

Clinical trials are one of the most sensitive areas of medical activity in bioethics, as they constitute experimental interventions on the human body. Central to this is the concept of informed and voluntary consent, as established by international bioethical documents and EU legislation [9, 24]. Violations of this principle – through misrepresentation, coercion, or exploitation of marginalized populations – are assessed in criminal-law terms as infringements on human autonomy and bodily integrity. Notably, the ECtHR has previously emphasized that the absence of adequate consent for medical treatment constitutes an interference with a person's private life under Article 8 of the ECHR [40, 41]. National criminal laws of EU member states establish liability for illegal human experimentation in codified form, rather than as a direct requirement to achieve serious outcomes, thereby emphasizing the preventive function of criminalizing experimental activities [5]. This corresponds to legislation designed to prevent abuses in scientific research.

Transplantation arguably provides the clearest example of the close intertwining of bioethics and criminal law. One of the central bioethical principles, set forth in Article 21 of the Oviedo Convention and Article 3 of the EU Charter of Fundamental Rights, is the prohibition of the commercialization of the human body and its parts. Legal prohibitions in this field are primarily aimed at eliminating organ trafficking, coercive extraction, and exploitation of donors in vulnerable social conditions. As highlighted in the literature, the social danger of such actions lies not only in the infliction of bodily harm but also in the societal perception of human dignity as an absolute value [42]. In the field of transplantation, the ECtHR has shown concern

regarding violations from a positive perspective, emphasizing the state's positive obligations to protect life and personal integrity. This includes establishing a comprehensive system in which criminal-law deterrence is effective [40]. This underscores the fact that criminal law in this area serves not only a punitive function but also a value-protective function.

The implications of assisted reproductive technologies raise several complex bioethical questions regarding the status of the embryo, the scope of permissible interventions in reproductive autonomy, and the prohibition of exploitation of the human body. EU legislation and ECtHR practice do not provide a uniform standard for determining when the right to legal protection of life begins, resulting in significant discrepancies in criminal-law decisions at the national level [39]. Criminalization in this area generally concerns the illegal creation or destruction of embryos, the coercive use of reproductive material without consent, and surrogacy arrangements involving aspects of human trafficking. Scholars correctly note that excessive criminalization may also restrict reproductive capabilities and foster "reproductive tourism" [1].

In conclusion, based on an analysis of key areas of biomedicine, the criminal-law response to violations of bioethical standards can be divided into two types, depending on the degree of risk posed to fundamental human rights. While clinical trials, transplantation, and assisted reproductive technologies demonstrate distinct models of criminalization, they are united by considerations of human dignity, autonomy, and bodily sovereignty. This provides a foundation for examining the role of legal policy in delineating the limits of criminal-law intervention.

### ***Legal policy and the limits of criminalization of violations of bioethical standards in medicine: European approaches and challenges of the 21st century***

The response of criminal law to violations of bioethical norms cannot be analyzed separately from the general legal policy of the state in the field of healthcare and human rights. In the 21st century, criminal law has become increasingly oriented toward humanization, subsidiarity, and proportionality, which entails a reassessment of the limits of criminalization in medical practice. This is especially relevant against the backdrop of a growing number of criminal proceedings against healthcare professionals and the emergence of so-called "defensive medicine". The purpose of this section is to examine the influence of EU legal policy and the case law of the ECtHR on the scope of criminal-law intervention in bioethics.

In contemporary criminal-law doctrine, it is generally accepted that criminal law should function as *ultima ratio* – the last resort in response to socially dangerous conduct. This principle is particularly relevant in medicine, as most bioethical violations can be adequately addressed through civil, administrative, or disciplinary law [5]. Increasingly, the legal policy of EU member states operates from the position that criminalization is effective only in cases of gross, intentional, or systemic violations of bioethical standards that pose a real threat to life, health, or human dignity. This reflects a trend toward differentiating responsibility and avoiding involuntary criminal sanctions for any deviation from medical or ethical norms [1].

Proportionality is a fundamental principle of legal policy in the field of criminal law and human rights. It entails aligning the severity of criminal-law measures with the nature and social danger of the violation to which a bioethical regime applies. As noted in the literature, excessive criminalization of medical practice has led to reduced quality of healthcare, avoidance of complex clinical decisions affecting patient outcomes, and the rise of defensive medicine [2].

The ECtHR emphasizes in its case law that criminal-law mechanisms must operate but should not create excessive pressure on professional medical practice. In cases of medical negligence, the Court repeatedly underscores the necessity of alternative, non-criminal means of legal protection [39]. However, limiting criminalization does not relieve states of their responsibility to provide criminal-law protection for bioethical values. Pursuant to Articles 2 and 8 of the ECHR, states have positive obligations to protect life and the physical and mental integrity of individuals. In cases of significant violations of bioethical standards, failure to provide a criminal-law response could itself constitute a breach of the Convention [40].

Therefore, legal policy must be developed to reconcile the interests of patients and medical professionals, ensuring that criminal law functions as an effective deterrent against the most egregious abuses in high-risk forms of biomedicine. To codify general approaches to the criminal-law response to such violations, a summary table is recommended (Table 2).

Principle	Content	Practical significance
Subsidiarity	Criminal law as <i>ultima ratio</i>	Preventing excessive criminalization
Proportionality	Punishment commensurate with the offense	Protecting the professional autonomy of physicians
Positive obligations	Duty of the state to protect human rights	Ensuring effective legal response

This table provides a comprehensive overview of how criminology, bioethics, and legal policy interact. Thus, 21st century legal policy in the field of criminal-law responses to bioethical violations stems from achieving a balance between effective protections of human rights and avoiding undue criminal pressure on medical actions. The criteria of subsidiarity and proportionality establish the limits of criminalization, while the ECtHR serves as a benchmark for states regarding positive obligations. This sets the conceptual groundwork for analyzing international bioethical standards and prospects for improving the criminal-law response.

### **International bioethical standards and directions for improving criminal-law responses to violations of bioethical norms**

Contemporary criminal-law protection of bioethical standards cannot be guaranteed without taking into account international standards and norms. The primary principles that define the limits of action in the medical sphere and the application of general criminal liability across countries are estab-

lished by international organizations and conventions. These sources can be divided into three main categories: the Council of Europe Convention [8] on Human Rights and Biomedicine (Oviedo Convention), the Charter of Fundamental Rights of the EU, and UNESCO texts on bioethics and human rights. These criteria provide a structural framework upon which successful legal policy formulation and differentiated criminalization of bioethical violations can be based.

Key international bioethical standards. The Oviedo Convention (1997) establishes fundamental principles regarding respect for human dignity, autonomy, the prohibition of eugenic procedures, and the commercialization of organs [42]. The Convention directly affects criminal law by defining socially dangerous actions that are subject to criminal prosecution within national legal systems. The EU Charter of Fundamental Rights enshrines rights to physical and mental integrity and prohibits the exploitation of the human body and commercial use of tissues and organs [41], providing mechanisms for legal and judicial practice at the member-state level. UNESCO declarations and documents, such as the Universal Declaration on Bioethics and Human Rights (2005), outline core ethical norms that become standards for assessing the criminal-law appropriateness of medical conduct [9]. Broadly, international standards contribute to the harmonization of national criminal norms, preventing “gaps” in legal regulation and serving as an effective reference point for strengthening criminal policy in biomedicine.

Despite extensive international regulation, critical gaps remain: conflicting definitions of the moment when legal protection of life begins (e.g., embryo, fetus, or zygote), differences in the criminal-law qualification of bioethical violations, and potential over- or under-regulation in certain areas (assisted reproductive technologies, clinical trials, transplantation). Addressing these challenges requires regulatory coordination and legal-policy solutions grounded in the principles of subsidiarity, proportionality, and positive obligations of the state.

Analysis of international standards and national practices suggests several directions for improvement:

- harmonization of national laws with international standards – adapting criminal-law provisions to the principles of the Oviedo Convention and the norms of the EU Charter;
- definition of clear criteria for social danger of actions – differentiating violations by the degree of harm and type of intent;
- preventive mechanisms and integration with legal policy – combining criminal-law responses with disciplinary, administrative, and civil measures;
- enhancing transparency and accountability in medical research – mandatory certification of clinical trials and monitoring compliance with bioethical standards.

These directions are summarized in Table 3. Moreover, this table provides an example of a comprehensive pathway for strengthening criminal-law responses and aligning them with international bioethical standards. An overview of international bioethical standards and their implementation in the EU and ECtHR demonstrates that criminal-law responses to violations of bioethical norms should be based on harmonization between international norms, national legal policy, and risk-man-

Table 3. Directions for improving criminal-law responses to violations of bioethical standards

Direction	Purpose	Expected effect
Harmonization of laws	Align criminal law with international norms	Promotes equality of standards in the EU and international law
Definition of criteria for social danger	Differentiate liability	Reduces excessive criminalization
Preventive mechanisms	Use of alternative measures	Increases effectiveness of law enforcement
Transparency and accountability	Monitoring of clinical and reproductive practices	Prevents violations of bioethical standards

agement mechanisms. If the strengthening of criminal liability is undertaken within the framework of proportionality, subsidiarity, and the positive obligations of the state, and aims to harmonize national approaches with international standards, it is also crucial to ensure effective protection of the rights of patients and medical professionals in the 21st century.

## DISCUSSION

The aim of this study is to provide a comparative analysis of criminal-law responses to bioethical violations in medicine within the contemporary European legal system. The findings demonstrate that bioethical principles – specifically the recognition of patient autonomy, the prevention of harm, the pursuit of justice, and respect for dignity – are transformed into criminal-law norms and guiding principles for medical practitioners and researchers to regulate conduct. The study also confirmed the heterogeneity of the integration between bioethics and criminal law: national systems and ECtHR practice create both opportunities and risks for the development of unified standards.

What distinguishes this research from previous studies is its three-level regulatory framework: criminal law, legal policy, and international bioethical conventions (EU, ECtHR, Oviedo Convention). Most prior work focused either on national criminal law or medical ethics, without systematically considering the integrated interaction between criminal liability, international norms, and legislative policy. This study compares three biomedical domains (clinical trials, transplantation, assisted reproductive technologies) from two different perspectives – ECtHR practice and EU philosophy – to provide guidance for determining general principles regarding criminalization and its limits.

The findings illustrate the necessity of balancing two dimensions of legal policy in the 21st century concerning criminal protection of bioethics. The result is a dual objective: to protect fundamental human rights while preventing excessive criminalization in bioethics that could impede medical science and practice. The principles of subsidiarity and proportionality, embedded in national legislation and ECtHR implementation, provide a foundation for more flexible arrangements that reflect both technological progress and 21st century ethical dilemmas.

A central topic of discussion is the challenge of balancing standards between international and national levels.

Although the Oviedo Convention and the EU Charter of Fundamental Rights provide frameworks for key principles, member-state practices show significant differences in the qualification of actions and the application of sanctions. The development of unified criteria for the social danger of bioethical violations, serving as an ethical benchmark across jurisdictions, reduces the risk of legal uncertainty. Therefore, the practical significance of this research lies in the intersection of criminal-law doctrine, legal policy, and international bioethical standards, forming a comprehensive perspective on how to respond to violations of bioethical norms. This framework serves as a foundation for further scientific and legislative progress.

## CONCLUSIONS

This study offers several significant findings and potential contributions to the formulation of criminal law and legal policy in bioethics. Bioethics has become an object of criminal-law protection because violations of autonomy, dignity, and the inviolability of patients constitute socially dangerous acts. This provides a normative basis for the incorporation of bioethics into criminal law. Criminal liability in medical disciplines should be determined by the degree and intent of the bioethical violation, as well as the specific biomedical field concerned. Clinical trials, transplantation, and assisted reproductive technologies reveal new patterns of criminalization that require adaptation.

21st century legal policy provides the foundation for applying criminal law in bioethics through the principles of subsidiarity, proportionality, and the positive obligations of the state. These principles help prevent both excessive criminalization and insufficient protection of patients. International bioethical norms (Oviedo Convention, EU Charter, UNESCO documents) serve as benchmarks for national legislation in addition to judicial practice, yet harmonization gaps remain substantial. This necessitates the establishment of clear indicators of social danger across all jurisdictions.

Additional research may focus on developing concrete criminal-law mechanisms for responding to bioethical violations, including preventive and non-criminal measures. Moreover, assessing the effectiveness of criminal liability across EU jurisdictions, particularly in light of emerging biomedical innovations, artificial intelligence in medicine, and digital health systems, is crucial. In conclusion, this study represents a unique contribution to the field of criminal law and legal policy: theoretical frameworks, international practice, and practical guidelines should be integrated to inform criminal-law responses to bioethical violations in the 21st century. The findings may serve as a starting point for reforms in policy, judicial development, and the teaching of bioethics and medical law.

## Conflict of interest

The authors declare no conflict of interest.

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# ЮРИДИЧНІ АСПЕКТИ РЕПРОДУКТИВНОГО ЗДОРОВ'Я

## CRIMINAL AND LEGAL RESPONSES TO VIOLATIONS OF BIOETHICAL STANDARDS IN MEDICINE: CHALLENGES FOR LEGAL POLICY IN THE 21ST CENTURY

### Literature review

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**Background.** The article proves that the relevance of the topic is due to the rapid development of biomedicine, the introduction of the latest medical technologies, the expansion of clinical trials, transplantology, assisted reproductive technologies, and the use of artificial intelligence in medicine, which significantly complicates the task of ensuring an appropriate balance between scientific progress, the protection of human rights, and public interests. In such conditions, violations of bioethical standards acquire not only medical and legal significance, but also criminal significance.

**Objective of the review:** to provide a comprehensive scientific and legal analysis of the mechanisms of criminal law response to violations of bioethical standards in the field of medical practice, taking into account the current challenges and trends in the development of legal policy in the 21st century, as well as to develop theoretically sound and practically oriented recommendations for improving criminal legislation and law enforcement practices in this area.

**Analysis of literary data.** The materials of the study are based on a methodological foundation formed by an integrated system of general scientific, special legal and interdisciplinary methods of scientific knowledge, the use of which is determined by the complexity of the problems of criminal law response to violations of bioethical standards in the field of medical practice. Particular attention is paid to the analysis of criminal offenses related to illegal medical interventions, violations of the procedure for conducting clinical trials, organ and tissue transplantation, manipulation of reproductive material, as well as forced or uninformed medical procedures. The need for improving criminal legislation and law enforcement practices, taking into account bioethical approaches, international standards, and the modern challenges of the 21st century, is justified.

**Conclusions.** It is summarized that the effectiveness of criminal law response to violations of bioethical standards can be ensured only under the conditions of implementation of a comprehensive legal policy that provides for a combination of preventive tools, coherent regulatory frameworks, and guaranteed protection of the rights and legitimate interests of both patients and medical professionals.

**Keywords:** bioethical standards, criminal and law responses, criminal legislation, legal policy, medical practice, clinical trials, transplantation, assisted reproductive technologies, human rights.

## КРИМІНАЛЬНО-ПРАВОВЕ РЕАГУВАННЯ НА ПОРУШЕННЯ БІОЕТИЧНИХ СТАНДАРТІВ У МЕДИЦИНІ: ВИКЛИКИ ПРАВОВОЇ ПОЛІТИКИ ХХІ СТОЛІТТЯ

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**Обґрунтування.** Актуальність теми статті зумовлена стрімким розвитком біомедицини, впровадженням новітніх медичних технологій, розширенням практик клінічних випробувань, трансплантології, допоміжних репродуктивних технологій, а також використанням штучного інтелекту в медицині, що значно ускладнює забезпечення належного балансу між науковим прогресом, захистом прав людини та публічними інтересами. У таких умовах порушення біоетичних стандартів набувають не лише медико-правового, а й кримінально-правового значення.

**Мета огляду:** здійснення комплексного науково-правового аналізу механізмів кримінально-правового реагування на порушення біоетичних стандартів у сфері медичної діяльності з урахуванням сучасних викликів і тенденцій розвитку правової політики ХХІ століття, а також розроблення теоретично виважених і практично орієнтованих рекомендацій щодо вдосконалення кримінального законодавства та правозастосовної практики у відповідній сфері.

**Аналіз даних літератури.** Методологічну основу дослідження становить інтегрована система загальнонаукових, спеціально-юридичних та міждисциплінарних методів наукового пізнання, використання яких зумовлено комплексністю проблем кримінально-правового реагування на порушення біоетичних стандартів у сфері медичної діяльності. Особлива увага приділялася аналізу складу кримінальних правопорушень, пов'язаних із незаконними медичними втручаннями, порушенням порядку проведення клінічних досліджень, трансплантацією органів і тканин, маніпуляціями з репродуктивним матеріалом, а також примусовими або неінформованими медичними процедурами. Була обґрунтована доцільність удосконалення кримінального законодавства та правозастосовної практики з урахуванням біоетичних підходів, міжнародних стандартів і сучасних викликів ХХІ століття.

**Висновки.** Ефективність кримінально-правового реагування на порушення біоетичних стандартів може бути забезпечена виключно за умов реалізації комплексної правової політики, яка передбачає поєднання превентивних інструментів, належно структурованого нормативного регулювання та гарантованого захисту прав і законних інтересів як пацієнтів, так і медичних працівників.

**Ключові слова:** біоетичні стандарти, кримінально-правове реагування, кримінальне законодавство, правова політика, медична діяльність, клінічні випробування, трансплантація, допоміжні репродуктивні технології, права людини.