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Ethical and legal aspects of editing a patient's genome for non-medical purposes

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Abstract. The need for knowledge of one's own biological nature was a crucial impetus for scientific-technological progress in the fields of molecular biology, chemistry, and genetic engineering, which soon turned into a way to control human genetic material and its evolution. Although the procedure for reconstructing the personality genome is designed to protect humanity from hereditary or oncological diseases, there is still a huge risk of using this technology to modify intellectual abilities or physical characteristics. The purpose of this study is to describe and characterize the moral, ethical, and legal factors that arise in using technology to correct a person's genetic code for non-medical reasons. Through systematic analysis and dialectical method, the current state of the legislative framework in the field of editing the biological material of the individual was investigated, while the generalisation method allowed identifying the main bioethical dilemmas associated with a certain problem. Exploring the possibility of changing the human genome through the prism of its interdependence with globalising metamorphoses in society, the key threats of the use of technology, its impact on the formation of the latest ethical standards, and compliance with the fundamental rights and freedoms of the patient were identified. Therewith, focusing on identifying gaps in the regulatory regulation of the human genome correction procedure, recommendations were made to improve the international legal foundation in this area of legal relations. In general, the chosen subject contains a considerable number of still unexplored aspects,

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so this study is designed to draw the scientific community's attention to the problem of editing a person's biological identity for non-medical purposes

Keywords: the fourth generation of human rights; nature of the individual; civil rights of the patient; innovative technologies; the right to privacy

Introduction

As a phenomenon of conceptual changes in society, humans are inextricably linked with the constant transformations of cultural, social and political landscapes, being the root cause of global metamorphoses, such as digitalisation or progress in genetics and genomics. Such transformations not only reflect the immediate needs of humanity but also radically reconsider international legal principles and fundamental legal categories, the leading of which is the concept of human rights. Throughout world history, the approach to understanding and applying fundamental freedoms of the individual has repeatedly undergone substantial modifications, adapting to new challenges and opportunities. Due to the fact that fundamental human rights simultaneously represent both the cause and mechanism for improving social standards, supplemented and developed in accordance with globalisation changes, they cannot be defined as a static or unchanging phenomenon but rather as a transgressive concept that has a dynamic and evolutionary character, not limited to the requirements of stability (Bufacchi, 2018). Thus, going beyond established interpretations and considering human rights in an unconventional context as a tool for achieving progress, individual rights and freedoms support a continuous debate about how unstoppable ideological and technological development obliges society to review generally accepted institutions, one of which is the right of the person to their own genome.

Considering the continuous development of innovative technologies in bioengineering and biochemistry and their gradual introduction into the population's life, the world community is faced with the task of protecting a person's biological identity and genetic health. With the advent of Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology, the issue of controlling one's genome has become more acute than ever, affecting moral and ethical dilemmas and regulatory aspects. However, despite the considerable potential of the human genome correction procedure as a potential "vaccine" against hereditary syndromes or oncological diseases, the risk of manipulating genetic information to modify the external characteristics or psychological aspects of a person is also on the agenda.

The chosen problem does not remain without the attention of the scientific community. For example, considering gene modification as a component of the fourth generation of human rights, S. Perepolkin *et al.* (2021) expressed concerns about the possibility of artificially improving the physical characteristics of patients. Therewith, investigating the prospects for the use of CRISPR, S. Komisarenko and S. Romanyuk (2020) emphasise that the technology is absolutely revolutionary in nature, but to fully realise all these opportunities and overcome moral absolutism, it is necessary to make it safer to use, and Yu. Turyanskyy (2020) highlights that funding in the areas of risk assessment, prevention, and management should be a priority in the field of gene editing. In the study by B. Ostrovska (2021), the impact of genome modification on human dignity was reviewed, concluding that in the context of maintaining a balance between the freedom of scientific research and the individual good of each individual, it remains relevant to conduct a diverse debate for making decisions about the moral and ethical acceptability of using genome editing technology. S. Sumchenko and O. Naumkina (2020) also focused on a philosophical understanding of the application of human genome reconstruction technology, highlighting the threat of commercialisation of biomedicine, which can create a new figure of a "business researcher". Since the possibility of DNA reconstruction not only creates some new legal conflicts, but also forces us to reconsider previously existing issues, it is quite appropriate to consider its impact on the reform of modern public standards (Krekora-Zając, 2020).

Thus, this study is aimed at analysing the legal framework in the field of human genome editing, and investigating existing ethical dilemmas associated with non-medical intervention in the human genetic code.

Materials and methods

The methodological foundation of the paper was the methods of system analysis, generalisation, and the dialectical method. Firstly, the generalisation method allowed characterising the moral and ethical aspects that society faces in connection with using human genome editing technology in general and for non-medical reasons in particular. The difference between the correction of somatic cells of a person and its germline and how such an intervention affects not only the patient but also the future generation was outlined. In addition, using the above-mentioned method, the place of the right to reconstruct one's own identity in the system of the fourth generation of human rights and their role in the formation of modern social standards, and the impact of technological innovations (primarily CRISPR) and globalisation challenges on the modification of the institution of individual rights, in particular, the category of somatic rights, were determined.

The method of system analysis provided an opportunity to examine the legal framework in the field of intervention in human genetic material, which includes the following normative legal acts: Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997), Universal Declaration on the Human Genome and Human Rights (1997), and International Declaration on Human Genetic Data (2003). Therewith, attention was focused on the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) (Council of Europe, 2019), and A review by the European Parliamentary Research Service of the legislation, governance, and principles of governance in the field of human genome editing regulatory act (Nordberg & Antunes, 2022). In addition, the method of system analysis identified the existing gaps in the legislative regulation of this field of relations, outlined the diverse positions of researchers on the expediency of its improvement, legal terminology, and regulatory requirements that should be highlighted in the content of leading transnational legal documents, which allowed providing recommendations for its reform in accordance with modern requirements.

Therewith, it is advisable to note the dialectical method, which was used to examine and consider diverse aspects of patient rights in the process of correcting the genetic code of the individual, in particular, the right to human dignity, non-discrimination, protection of personal data, and their relationship with the formation of public ethical standards. Different standpoints were presented regarding the correlation of the identified fundamental human benefits of using the DNA editing procedure in the context of non-medical intervention. In addition to international legal acts, the necessary materials for this study were the papers of Chinese, Korean, African, Polish, German, Spanish, Portuguese, Hungarian, Belgian, Turkish, British, American, Canadian, and Ukrainian researchers, helping to objectively study the subject of artificial manipulation of human biological nature through its bioethical and moral components and regulatory aspects.

Results

The scientific and technological revolution, cultural assimilation, achievements in the fields of biochemistry, medicine and bioengineering, the speed of expansion of cyberspace – globalisation challenges cover a considerable range of transformational processes in almost every area of the functioning of society, which generates not only the reconstruction of human legal consciousness but also a rethinking of the correlation and impact of innovations on the life of the population and individuals in particular. The spread of a new paradigm never occurs instantly, especially in the context of interference in the field of private life or health, and therefore, the formation of a thoroughly new generation of human rights, the emergence of which is primarily associated with the development of the latest technological achievements can be stated (Hilbert, 2020). Although the fourth generation of human rights is still in its infancy, it has substantially enriched the system of human rights and freedoms. There are many researchers, including Ukrainian authors O. Ivanii *et al.* (2020), emphasising that the latest generation of human rights is associated with a specific object – a person, namely their body and organism, and despite the maintenance of this concept, it is advisable to supplement the above opinion, which will clearly demonstrate the unbreakable link between the international challenges of our time and the expansion of the category of human rights and the issue of their provision. Figure 1 shows the defining distribution of new rights, which can also be described as rights to a safe environment, digital and somatic rights.

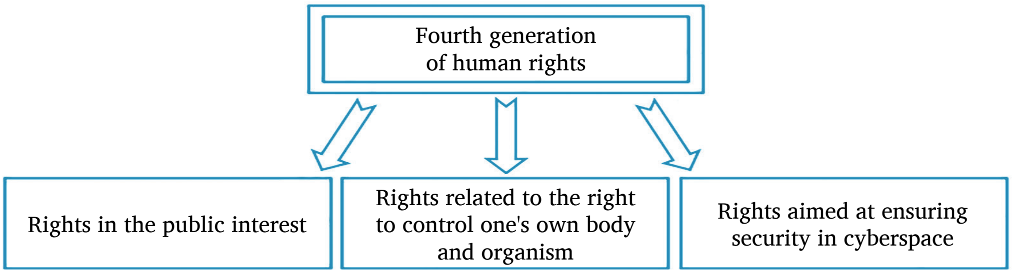

Figure 1. Fourth-generation classification of human rights

Source: compiled by the authors

An example of modern rights to a healthy environment is the so-called Mother Earth rights, recognised by the courts of Ecuador and Bolivia, which, although they do not interpret a person as the addressee of these rights, simultaneously serve as a tool for ensuring the human right to clean air, water, soil and a method of combating climate change (Berros, 2021). In turn, the functioning of digital (virtual) rights, for example, the right to digital self-determination or security in cyberspace, is a consequence of the continuous spread of information-communication technologies and offences committed through their application. Despite the fact that the subject of digitalisation and its impact on human life and its fundamental freedoms causes considerable interest among researchers (Brkan *et al.*, 2020), calls for the protection of virtual rights of the population have already led to numerous resonant projects and political statements at the national and transnational levels (Karppinen & Puukko, 2020), just the last group of rights of the new generation – somatic rights – require additional discussion because their implementation affects not only scientific-technological progress but also issues of law, ethical perception, and even religion.

Unlike other legal categories, somatic rights interact most closely with the person themselves because they are directly related to the right to dispose of one's own personality, so this should include the right to artificial reproduction, cloning, surgical sex correction. Special attention should be paid to the somatic right to one's own genome, or rather the ability and right to edit it, which, due to medical, legal, and moral uncertainty, has not yet been properly disclosed. B. Prainsack (2014) defines a "genome" as "any data representing the sequence of nucleotides in our genome", while A.D. Goldman and L.F. Landweber (2016) define the concept of "genome" as an information core, which often, but not necessarily, manifests itself as DNA, which programmes a diverse range of functional capabilities and contributes to the functioning of the body. However, scientific discoveries in chemistry, genetic engineering, and microbiology are now forcing society to consider the genome category not only in terms of the information needed to create cells and maintain an organism but also as a method of manipulating the genetic code of a person.

Recently, the issue of editing the human genome is no longer a purely theoretical hypothesis since its relationship with gene or biotechnology is dichotomous because, on the one hand, the procedure for correcting the biological nature of the individual determines the further course of application of innovative technologies, whether limiting their use, or encouraging their development, but, on the other hand, the latest changes in the fields of cell engineering or genetics are the factor that creates opportunities for manipulating human genetic material, which can be used for both medical and non-medical purposes. How the benefits are used will ultimately depend on the efforts made both in the laboratory and outside it (Carroll, 2016). It is advisable to agree with the statement of the Chinese researcher S. Liu (2020), who compared personality genome editing technology with a double-edged sword, correlating evident advantages with substantial disadvantages. For example, the genome correction procedure allows replacing a "damaged" due to an inherited mutation gene, thereby contributing to the treatment of diseases such as immunodeficiency virus, haemophilia, or cystic fibrosis, and is a method of modifying a person's physical characteristics or cognitive abilities. In other words, this technology can be used to treat individuals and improve or completely change their physical abilities before or after birth (Perepolkin *et al.*, 2021). Thus, the issue of legal regulation of the procedure for the transformation of human hereditary material is more acute than ever since from now on, the procedure for genome reconstruction can be not only a limited medical tool but also a factor in the emergence of transnational moral and ethical dilemmas.

Notably, the subject of editing the personality genome is marked by a rather limited legislative foundation, which creates a huge opportunity for the abuse of genetic modification. It is impossible not to mention the Universal Declaration on the Human Genome and Human Rights (1997) and the International Declaration on Human Genetic Data (2003), but these documents only focus on the implementation of fundamental human rights in the context of genetic research. The only act, the norms of which directly regulate the scope of personality DNA correction, is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997). Article 13 of the Convention establishes in its text the possibility of editing the genome of a person only for medical, diagnostic, or preventive purposes and only if its purpose is not to modify the genetic material transmitted to descendants, so it is appropriate to investigate this provision in more detail. First, from the content of Article 13, it can be concluded that, although there are certain restrictions, the activity in question does not expressly prohibit genetic engineering. Secondly, by not allowing the procedure of editing the germ line of the genome (modification of genetic material passed on to descendants), the legislator does not recognise illegal interference with the human genome in its somatic cells, the differences of which are clearly demonstrated by Figure 2.

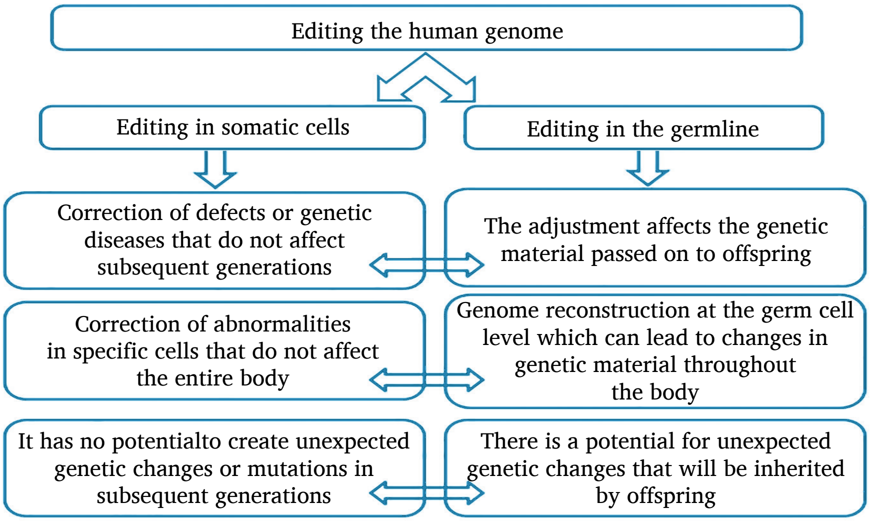

Figure 2. Genome editing discrepancies in somatic and germ cells

Source: compiled by the authors

E. Birney (2023), deputy director general of the European Molecular Biology Laboratory (EMBL), emphasises that there is a substantial difference in understanding between modifying damaged genes – or editing DNA – and "improving" the potential lives of humans and their descendants. It is important to understand that such differences between varieties of genome editing procedures are essential from the standpoint of legislation, but due to the lack of proper legal regulation, this only creates legal and bioethical dilemmas, one of which is the lack of at least an indicative list of diseases that allow interference with the genome of a person. In other words, the interpretation of medical or non-medical intervention is not conducted within the framework of regulatory permits or prohibitions but depends on laboratories and their employees. For example, pigmented neuralgic nevus, which manifests itself in the form of pigmented spots on the skin and does not affect the functional capabilities of the body in any way, is a genetic disease, so it is de facto one of the candidates for gene modification, but serves as a more potential example of improving external characteristics than changes in internal characteristics of the body. The practice of modifying physical characteristics for the better completely destroys the principle of individuality, which not only threatens the emergence of criteria for an ideal person, but also ignores the issues of implementing the individual's fundamental rights (Perepolkin *et al.*, 2021).

Many researchers, including R. Andorno (2002), emphasise the absolute importance of fundamental human rights in the context of the permissibility of using innovative biological technologies for a particular person. According to Article 10 of the Universal Declaration on the

Human Genome and Human Rights (1997), no research, especially in the field of genetics and medicine, should take precedence over the basic freedoms of each individual. In the context of interference with the human genome, which determines its individual characteristics, the issue of protecting patient autonomy is raised, which includes respect for human dignity, confidentiality of personal information, and discriminatory consequences. Although it is advisable to cite the opinion of B. Gregg (2022), who rejects the idea that individual rights and freedoms somehow arise from genetic identity, it is as important to consider the hypothesis that its destruction can spoil the unique biological nature of the individual. Similarly, the risk of commercialisation, in which private businesses focus their efforts on modifying a particular person's mental or physical characteristics for their own enrichment, and human genes or cells become objects of patenting, should not be neglected (Shozi, 2021). Therewith, one of the main factors of dignity is the patient's privacy because there are such issues as ways to obtain the consent of a person or their refusal, the prospect of leaving the study, collecting personal information about the subject, predisposition to a certain disease (Niemiec & Howard, 2020). In turn, T. Ishii and I. de Miguel Berian (2019) draw attention to the fact that children who were conceived using genetically modified cells or embryos are subject to long-term monitoring and surveillance, which threatens not only the right to privacy but also creates opportunities for unauthorised access to the subject's personal data. Therewith, due to the uniqueness of combinations of genetic variants, confidentiality in the exchange of personal data should be conducted considering the prevention of potential discriminatory and social consequences (Terzi, 2018). In particular, it is not only about preventing the formation of stigma and restrictions in relation to a certain group of people but also about creating an elite society with "improved" external and internal characteristics.

Thus, it is reasonable to emphasise that changing a person's genetic code and minimising potential adverse consequences requires further discussion and regulatory regulation. Ensuring a balance between scientific and technological progress and the protection of fundamental human rights is the leading and most difficult task facing the international community today. Non-medical genome editing and continuous innovation development are accompanied by considerable ethical and legal conflicts that require coordinated cooperation between legislators, researchers, and the public, both on the national level and internationally.

Discussion

The introduction of the latest technologies and scientific research related to them is quite difficult to control because the originality effect causes a lack of legal regulation and public analysis. Therefore, it becomes possible to accurately assess the potential risks of an individual innovation only over time when the latest tools become part of the culture and human infrastructure. The procedure for correcting a person's genetic code causes considerable discussion, mainly focusing on its consequences and public attitudes. Notably, the idea of treating hereditary diseases itself has a huge potential in the context of improving the healthcare sector. For example, Korean researchers, including S.B. Moon *et al.* (2019) note the positive effect of genetic engineering, which now opens up new therapeutic prospects for the treatment of almost four thousand rare genetic diseases. Similarly, this opinion is supported by J. Lee *et al.* (2020), emphasising that editing the genetic code not only slows down the progression of genetically determined diseases but also includes gene therapy for patients with difficult-to-treat diseases such as cancer.

However, despite the considerable possibilities of gene modification, it is worth agreeing with the reasoning of the Jordanian researcher A.M. Khalil (2020), highlighting concerns that bioethical and regulatory conflicts will only increase with the rapid revolution in biotechnology, given the possibility of manipulating the human genetic code and the unpredictability of this procedure. Although genetics allows recognising a gene in the genome associated with the disease, there is no absolute guarantee that its reconstruction will lead to the desired result. Therewith, interference in the work of the genome, the target orientation of which does not correspond to the medical purpose, there is a potential (and very real) probability of having children with improved traits, which will not only lead to the depreciation of children with disabilities but also endanger the very essence of genetic diversity (Espinosa, 2019).

Therewith, the lack of clear legislative regulation aimed at regulating the procedure for editing human DNA and establishing infallible rules for the use of gene modification technology is of great concern. According to the above-mentioned data, the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (1997) relies only on the transnational normative consolidation of the correction of the personality genome, which, however, leaves a considerable number of legal gaps. Despite the indisputable lack of regulatory control, experts have not yet unanimously agreed on its regulation. In general, the issue of creating specialised legislation does not cause discussions because it is the last line of defence of social management (Liu, 2020). However, according to the Polish researcher D. Krekora-Zając (2020), the belief that legislative regulation will prohibit editing human genes in an extra-medical area, looks rather illusory, and O. Feeney *et al.* (2021) argue that although genome reconstruction requires regulation and, in the optimal variant, it will include the latest international legal framework, the path to it is still too long, but even after appropriate adoption, it will lack satisfactory flexibility.

Notably, the steering committee for Human Rights in the fields of Biomedicine and Health (CDBIO) (2022) undertook to examine the existing moral, ethical, and legal problems associated with the technology of editing the human genetic code, which could indicate the need to improve or completely modify Article 13 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Council of Europe, 2019). The European Parliamentary Research Service also puts on the agenda the issue of balancing potential benefits and unintentional harm to the patient, controlling gene editing technology and combining public values with the area of using these innovations, but so far, such normative consolidation remains only at the level of public and scientific discussions (Nordberg & Antunes, 2022). Currently, no country in the world has recorded direct permission to reconstruct the genome in the germ line (Baylis *et al.*, 2020), however, as Yu. Turianskyi (2020) rightly pointed out, purely prohibitive prescriptions cannot achieve favourable consequences.

Thus, the importance of a quick regulatory regulation of the procedure for modifying the genetic inheritance of a person leaves no doubt because a considerable list of critical components has not yet found a proper settlement – justification for the punishment for correcting genetic material for non-medical reasons, whether it is the patient's consent, including such aspects as methods of obtaining it, its volume, the list of persons authorised to provide it. Given the potential for manipulating the individual biological code of a person, the transformation of the methodology of legal management of genetic engineering technologies is a key factor in minimising negative consequences for individuals and society in general. Attention should also be paid to the lack of terminological interpretation of the concept of "non-medical purpose of influencing the genome of a person" because views on where to draw the line between preventive, therapeutic and non-medical intervention differ in different cases, which, in turn, affects the determination of the level of legality or lawlessness in the implementation of this procedure (Waltz *et al.,* 2021).

In addition, given the profound impact of genome editing on the patient's fundamental rights and Freedoms, a substantial number of researchers suggest using an approach that primarily establishes guarantees for the protection of human rights to direct control over the reconstruction of the genetic code of a particular individual (Wang *et al.*, 2022). It is important to emphasise that the human rights system does not veto gene modification but rather is a tool for integrating two fundamental factors – responsibility for illegal interference in human biological nature and compensation for potential harm and compliance with international legal standards in the field of human rights protection. The Portuguese researcher V.L. Raposo (2019) put forward the idea that using human dignity as a reason to prohibit editing gene information (or banning any other practice) is tempting only because of the simplicity of the argument. This statement can be supported only in the context of considering genetic engineering as a method of treating, for example, cancer, diabetes, or tuberculosis, but given the technological possibilities of artificial modification of psychological, physical, behavioural, or cognitive aspects of an individual, which in no way affect the functional abilities of the body, this reasoning requires a comprehensive study, with the involvement of experts in the field of medicine, biology, psychology, law, and civil society.

Despite the limitless possibilities of progress that the latest methods of correcting the human genetic code bring, new socio-ethical, moral, and bioethical dilemmas are constantly emerging, which can be a warning about their use (Ayanoğlu *et al.*, 2020). It seems impossible to find a consensus on the ethics and legitimacy of the procedure for modifying the human genome, especially its implementation for non-medical reasons, for military, or discriminatory purposes. The lack of a legislative foundation, the continuous development of genetic engineering, the practical lack of transparent practices, and substantial concerns about the inevitable harm to individual rights and future generations prevent the formation of a unified policy to protect human genetic health and ensure control over the confidentiality of genetic data and their own genome. The international community should establish a stable dialogue between experts in the relevant fields and civil society and achieve the implementation of moral, bioethical and legal analysis in further scientific research.

Conclusions

The main purpose of writing this paper was to investigate the regulatory and bioethical factors that arise in connection with using human genome editing technology for extra-medical reasons. Thus, summarising all of the above, it is advisable to summarise the following results.

The legal regulation of the procedure for reconstructing the patient's genetic code at the international level contains a considerable number of gaps that prevent the formation of a holistic policy for regulating and monitoring the process of gene modification. The lack of an extensive legislative framework that would focus on preventing and controlling potential risks associated with artificial manipulation of the human genome is of considerable concern: legal interpretation of the concept of "interference for non-medical reasons", an indicative list of applicants for modification, obtaining patient consent, imposing penalties for illegal interference in the functioning of the human body, compensation for damage in the event of adverse consequences. The legal consolidation of each of these categories is urgent since they are not only a component of the management mechanism for the use of the latest technologies but also those factors that cause an urgent need to implement fundamental human rights in scientific progress in the field of genetic engineering and biomedicine.

Although the international community focuses on establishing effective tools for protecting the rights of each individual and society in general, it is possible to achieve a positive result only by applying a comprehensive approach that provides for both the establishment of the latest standards, rules, and prohibitions in accordance with globalisation changes, and the reform of the existing legal apparatus – from civil law to legislation regulating the conduct of clinical experiments.

The moral component of the procedure for correcting the patient's genome is still on the agenda, especially in the context of intervention for non-medical purposes, because the issue of preserving the unique biological nature of the individual affects the issues of ethical standards, and the preservation of human dignity or intervention in the evolutionary process. Changes in physical characteristics or cognitive abilities create a potential risk of irreparable damage to the individual's identity in the long run, so it is important to maintain a balance between introducing innovative technologies in human infrastructure and preserving bioethical principles. In general, the issue of editing the human genome for non-medical purposes remains a poorly researched subject that requires further public discussion in terms of ethical perspectives, medicine, legal aspects, and philosophy.

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Conflict of interest

None.

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Етичні та правові аспекти редагування генома пацієнта в немедичних цілях

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Анотація. Потреба в пізнанні власної біологічної природи стала вирішальним поштовхом до науково-технологічного прогресу в галузях молекулярної біології, хімії та генної інженерії, що невдовзі перетворилося на спосіб контролювання генетичного матеріалу людини та її еволюції. Хоча процедура реконструювання геному особистості покликана захистити людство від спадкових чи онкологічних захворювань, залишається колосальний ризик використання цієї технології задля модифікації інтелектуальних здібностей чи фізичних характеристик. Мета проведення дослідження – окреслити та схарактеризувати морально-етичні й правові фактори, що постають у зв’язку з використанням технології коригування генетичного коду особи з немедичних міркувань. За допомогою системного аналізу та діалектичного методу досліджено стан законодавчої бази у сфері редагування біологічного матеріалу особистості, водночас метод узагальнення дозволив розкрити основні біоетичні дилеми, пов’язані з визначеною проблематикою. Досліджено можливість видозміни геному людини через призму її взаємозалежності з глобалізаційними метаморфозами в суспільстві, окреслено ключові загрози застосування технології, її впливу на формування новітніх етичних стандартів та дотримання основоположних прав та свобод пацієнта. Акцентовано увагу на виявленні прогалин у нормативному регулюванні процедури корекції людського геному та надано рекомендації з приводу вдосконалення міжнародно-правового фундаменту в окресленій сфері правовідносин. Загалом обрана тематика містить низку недосліджених аспектів, тож стаття покликана привернути увагу наукової спільноти до проблеми редагування біологічної ідентичності людини в позамедичних цілях

Ключові слова: четверте покоління прав людини; коригування біологічної природи особистості; цивільні права пацієнта; інноваційні технології; право на приватність