



## INTERNATIONAL LAW PRINCIPLES IN THE CONTEXT OF ADVANCING GENETIC TECHNOLOGIES

### *PRINCÍPIOS DO DIREITO INTERNACIONAL NO CONTEXTO DO AVANÇO DAS TECNOLOGIAS GENÉTICAS*

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#### ABSTRACT

**Objective:** The objective of this study is to analyze the current legal status and regulatory framework of genetic technologies, and to explore pathways for the development and formation of a comprehensive regulatory environment for genetic technologies, focusing on human cloning, genetic research, assisted reproductive technologies, and the handling of biological samples for diagnostic purposes.

**Methods:** The research employs the dialectical method of scientific inquiry, formal logic, historical analysis, and system-structural methods. It examines relevant international treaties, interdisciplinary scientific literature, selected aspects of foreign legislation, and a landmark judicial decision of the Supreme Court of Brazil on the legal use of embryonic stem cells for therapeutic purposes.

**Results:** The study highlights the evolving significance of general and specific principles in international law, such as the principle of sovereign equality of states and the principle of equal rights and self-determination of peoples. These principles are being redefined by concepts like biosovereignty and genomic sovereignty, and by the challenges posed by genetic editing technologies like CRISPR. The analysis





underscores the need for national and international principles and standards in the field to align, potentially encompassing erga omnes obligations.

**Conclusions:** The analysis confirms the necessity for national and international principles and standards that govern this field to align, potentially encompassing erga omnes obligations. This alignment is essential to strike a balance between the potential benefits and risks associated with the global-scale deployment of genetic (genomic) technologies.

**KEYWORDS:** Modern international law, principles of international law, peremptory norms of general international law (jus cogens), erga omnes obligations, legal regulation in genetics, human genome, genetic technologies.

## RESUMO

**Objetivo:** O objetivo deste estudo é analisar o status jurídico atual e o arcabouço regulatório das tecnologias genéticas, e explorar caminhos para o desenvolvimento e formação de um ambiente regulatório abrangente para tecnologias genéticas, com foco em clonagem humana, pesquisa genética, tecnologias de reprodução assistida e o manejo de amostras biológicas para fins diagnósticos.

**Métodos:** A pesquisa emprega o método dialético de investigação científica, lógica formal, análise histórica e métodos sistêmico-estruturais. Examina tratados internacionais relevantes, literatura científica interdisciplinar, aspectos selecionados da legislação estrangeira e uma decisão judicial emblemática do Supremo Tribunal Federal do Brasil sobre o uso legal de células-tronco embrionárias para fins terapêuticos.

**Resultados:** O estudo destaca a importância crescente dos princípios gerais e específicos do direito internacional, como o princípio da igualdade soberana dos Estados e o princípio dos direitos iguais e autodeterminação dos povos. Estes princípios estão sendo redefinidos por conceitos como bio-soberania e soberania genômica, e pelos desafios colocados pelas tecnologias de edição genética como o CRISPR.

**Conclusões:** A análise ressalta a necessidade de que os princípios e normas nacionais e internacionais no campo se alinhem, potencialmente abrangendo obrigações erga omnes. Este alinhamento é essencial para equilibrar os potenciais benefícios e riscos associados ao uso em escala global das tecnologias genéticas (genômicas).

**PALAVRAS-CHAVE:** Direito internacional moderno, princípios do direito internacional, normas imperativas do direito internacional geral (jus cogens), obrigações erga omnes, regulação jurídica em genética, genoma humano, tecnologias genéticas.

## 1 BACKGROUND ISSUES





The global advancement of genetic technologies and their practical application spanning various aspects of human life is progressing rapidly, transcending national borders of international legal entities, namely states.

Prominent experts in molecular biology assert that genetic engineering, particularly in the realm of human health, offers the potential to reveal an individual's genetic information, such as predispositions, diseases, and associated risks. However, it is imperative that humanity acknowledges the inherent dangers associated with accessing and utilizing this extensive genetic information and the potential outcomes it could precipitate<sup>1</sup>.

Lawmakers, both at the national and international levels, along with commercial sector representatives and individual citizens, have grown accustomed to the capabilities of genetic technologies. This familiarity stems from an interest in the apparent benefits, profits, and achievements these technologies offer, necessitating the establishment of acceptable boundaries for the practical application of the "blessings" of these genetic advancements. This raises a critical non-legal question: to what extent and for what ultimate purpose should these technologies be employed? Is the goal to achieve immortality?

Currently, the international community, businesses, and individuals across various legal systems and religious backgrounds face a pressing issue: determining the fundamental principles and norms that will govern the activities of various stakeholders in the domain of breakthrough genetic technologies. The key challenge lies in identifying a common framework for the legal regulation of activities in the field of genetic technologies.

The authors of this article pose a critical question: can law, particularly international law, facilitate the acquisition of benefits in this emerging sphere without compromising humanity's fundamental self-understanding? We contend that public international law, with its extensive history of theoretical and practical development, can provide a foundational platform for interaction, balancing the interests of all participants in the international arena concerning genetic technologies.

To this end, we have examined the nature, history, and content of select principles of international law, along with the nuances of both international legal and national regulatory frameworks in the field of genetic technologies. In this context,

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<sup>1</sup> See: *Skryabin K. G.* The world will be saved by GMOs and genetic engineering. URL: <https://www.fontanka.ru/2013/10/04/166/>.





genetic technologies encompass all innovative, breakthrough developments in this domain. These may be referred to by various terms such as “genomic technologies”, “genetic technologies”, or “biomedical technologies”, all of which are interrelated.

The study concentrates on the contemporary genetic technologies sector, specifically exploring the international legal relationships that are arising within this domain. The research entails an examination of existing, as well as potential, principles of international law established by the global community to oversee these emergent legal connections. The ultimate goal is to establish a cohesive legal framework to govern genetic technology-related activities effectively.

Given the rapid advancement of genetic technologies, there is a clear need to establish common rules for the interaction of all participants in international relations, ensuring that these rules do not harm humanity, even in the long term. Additionally, a new approach is required to ensure the biosafety of individuals, citizens, and society as a whole, while respecting the state borders of international legal subjects.

The question arises: whether the international community presently acknowledges the requisite protection of constitutional and civil human rights as a result of scientific investigations in this field and their ensuing implementations.

In addition to legal considerations, genomic research introduces numerous socio-ethical and moral conflicts. The benefits of such research are accompanied by potential risks to human and public health, the environment, and ecology. For instance, bioethical and moral controversies surrounding genetic screening include issues such as data confidentiality versus information disclosure for biosafety, personal choice versus societal coercion, voluntary versus compulsory screening, and genetic discrimination and stigmatization.

It is crucial to recognize that these issues arise during a period marked by a crisis of human values. Although this crisis may initially appear unrelated to the international legal regulation of genomic research, such a perspective is overly simplistic. The underlying ethical dilemmas are intrinsically linked to the broader context of legal and regulatory frameworks governing genetic technologies.

Experts observe that humanity is currently undergoing a crisis in traditional and classical forms of social organization, ranging from family structures to state and international communities. This crisis is evidenced by the breakdown of long-standing international norms and rules that have historically governed the actions of states and international organizations. The fragmentation of the international community,





particularly in sectors like high-tech medicine, further exacerbates this crisis. Nevertheless, despite various disruptions and current distortions<sup>2</sup>, the crucial role of international law in *consolidating* and organizing vital services such as national healthcare cannot be overstated.

To comprehend the nature of contemporary international relations and address their crisis, it is essential to consider the philosophical integration of three categories: “consciousness”, “culture”, and “globalization”. The trajectories of distinct epistemically defined cultural domains, both large and small, shape the modern world order. In analyzing the ongoing abnormalities at global, regional, and national levels, it becomes apparent that resolving these international relations crises necessitates new approaches and strategies. In this context, the underlying issues are not superficial but deeply embedded, rooted in cultural and civilizational factors rather than forceful, political, or socio-economic ones. These issues have a centuries-old prehistory<sup>3</sup>.

To establish relationships between the internal compartments of a given space with various combinations of spatial relations, as illustrated by Euler’s circles, it is essential to consider this space as closed<sup>4</sup>. In this context, the closedness of space refers to the planet Earth, and the internal compartments represent the legal relations among participants in international affairs.

Given this framework, it is evident that modern genetic technologies require appropriate legal regulation, integrating the system of biological knowledge with the system of human values<sup>5</sup>.

## 2 INTERESTS OF PARTICIPANTS IN INTERNATIONAL GENETIC TECHNOLOGIES: IDENTIFYING COMMON GROUND FOR FUTURE LEGAL REGULATION

<sup>2</sup> See: *Kholikov I. V., Milovanovic A., Naumov P. Yu. V., Milovanovic A., Naumov P. Yu.* Dynamics of the functioning of international law in the transformation of the modern world order: postclassical approach // *Journal of Russian Law*. 2022. V. 26. № 11. P. 133-140. DOI: 10.12737/jrl.2022.122

<sup>3</sup> See: *Smirnov A. B.* Omnihuman vs. panhuman. 2nd ed. M., 2022. p. 5, 12-13.

<sup>4</sup> See: *Smirnov A. B.* Omnihuman vs. panhuman. 2nd ed. M., 2022, p. 58

<sup>5</sup> See: *Khabrieva T.Y., Chernogor N.N.* The Future of Law. The Legacy of Academician V.S. Stepin and Legal Science. M., 2020; *Khabrieva T. Ya.* Projections of the development of convergent technologies in law // Transformation of the paradigm of law in the civilizational development of mankind: reports of the members of the Russian Academy of Sciences / ed. by A. N. Savenkov. M., 2019.





The global interest in applying the achievements of modern genetic technologies is clear, as health has become a central goal of human existence, increasingly dependent on medical advancements. This has initiated the process of *biomedicalization* of society, where the influence of medicine extends into the realm of body transformation<sup>6</sup>.

Therefore, researching the interests of all legal subjects involved in genetic technologies, particularly from the perspective of subsequent international legal regulation, is a highly pertinent and urgent issue.

Legal literature delineates centrifugal, centripetal, multidirectional, and other developmental interests of individuals and societies. In this context, law undertakes the significant and complex task of identifying, coordinating, and balancing these interests, while safeguarding socially beneficial interests of individuals, societies, states, ethnic groups, and the international community. The concept of legitimate interests emerges to reflect the social dynamics of specific historical epochs. In certain phases of civilization, there is a notable rise in material hedonism, the pursuit of pleasure intertwined with the expansion of the entertainment industry, and the quest for maximal material advantages<sup>7</sup>.

Defining the boundaries within which advancements in genetic technologies align with national interests of states, as well as other participants in international relations and the global community, becomes crucial. Can international law, in conjunction with relevant scientific expertise, delineate and enforce these boundaries alongside existing frameworks?

Interests in international law are intricately linked with national interests, which encompass the qualitative attributes defining a nation as an autonomous and self-sustaining entity. These attributes establish long-term and stable objectives crucial for ensuring the nation's survival and maintaining its cultural identity<sup>8</sup>.

From a legal standpoint within the interstate system, experts emphasize the importance of balancing rights and obligations rather than focusing solely on interests or power dynamics. The concept of national interest has evolved beyond its original role of safeguarding national security, emerging as a distinct factor in shaping

<sup>6</sup> See: Law and biomedicine: monograph / ed. by F. V. Tsomartova. M., 2021. p. 9.

<sup>7</sup> See: Interests in the mechanism of public power: problems of theory and practice: a monograph / ed. by Y. A. Tikhomirov. M., 2023. p. 12, 20, 74.

<sup>8</sup> See: Commentary to the Constitution of the Russian Federation (article-by-article): taking into account the changes approved during the all-Russian vote on 1 July 2020 / ed. by T. Y. Khabrieva. M., 2021.





international relations. Consequently, the alignment of interest and law is not always synonymous. Nonetheless, international law incorporates various legal mechanisms designed to safeguard the collective interests of the global community. These mechanisms include norms such as *jus cogens* and obligations *erga omnes*<sup>9</sup>.

### 3. SCIENTIFIC RESEARCH IN GENETIC TECHNOLOGIES AND THEIR REGULATORY BOUNDARIES

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, commonly known as the Oviedo Convention, was opened for signature on 4 April 1997 in Oviedo, Spain. It stands as the sole legally binding international instrument dedicated to safeguarding human rights in the realm of biomedicine.

Article 15, Chapter V of the Oviedo Convention, titled “Scientific Research”, establishes a fundamental principle: “Scientific research in biology and medicine shall be conducted freely, subject to the provisions of this Convention and other legislative instruments ensuring human protection”. Furthermore, Article 16 of the Oviedo Convention states: “Research involving human subjects may only proceed under the following conditions:

- (i) When no alternative methods of comparable efficacy exist;
- (ii) When the risks to participants do not outweigh potential benefits;
- (iii) The design of the proposed research has been approved by the competent authority after an independent review of the scientific validity of the research, including the importance of its purpose, and a multilateral review of its ethical acceptability;
- (iv) Ensuring informed consent of the person serving as a test subject and the protection of subjects' rights under the law;
- (v) Obtaining explicit, specific written consent.

Article 18 of the Oviedo Convention prohibits the creation of human embryos for research purposes, and Article 21 prohibits financial gain from the human body and its

<sup>9</sup> Interests in the mechanism of public power ... p. 226-227, 234.





parts: “The human body and its parts shall not be exploited for financial gain”. The intricate nature of scientific research and its legal delineation, both within national laws and international regulations governing science, necessitates careful consideration. It is pertinent to highlight UNESCO's role, as a specialized agency of the United Nations focusing on scientific, cultural, and educational matters, with membership from the majority of countries worldwide<sup>10</sup>.

#### 4. GENETIC (GENOMIC) DATA IN INTERNATIONAL LEGAL REGULATION

Modern genetic technologies rely on pertinent information. For precise legal definition and regulation, the choice between “genetic” and “genomic” information requires careful consideration of their historical usage. Biologists, geneticists, and philosophers originally coined these terms, with “genetic information” predominating before 1990, and “genomic information” gaining prominence thereafter, coinciding with the initiation of the Human Genome Project.

Understanding “genetic” or “genomic” information involves several criteria: the biological sample's origin, its fixation and storage locations, and its intended purposes<sup>11</sup>. Specialists stress the incompatibility between approaches to genetic data, viewed both as deeply personal and *transgenerational*, carrying familial experiences across generations. Proposals have been made to regard genetic data as *pluopersonal*, facilitating legal frameworks that safeguard individual health and life while preserving the genetic heritage of descendants and ethnic communities alike.

Undeniably, genetic data possesses distinct characteristics that differentiate it from other personal data, warranting special legal status due to its high potential for discrimination. Consequently, the issue of legally protecting genetic data becomes critically relevant<sup>12</sup>, considering the diverse interests of stakeholders involved in relevant legal relationships.

<sup>10</sup> For more details see, for example: *Chetverikov A.* O. Science as a legal category: a comparative legal study // *Vestnik of O. E. Kutafin University (Moscow State Law Academy)*. 2019. № 4. p. 55-62.

<sup>11</sup> See: *Maleina M. N.* The concept and classifications of genomic (genetic) information // *Lex russica*. 2020. T. 73. № 7. p. 50-58. DOI: 10.17803/1729-5920.2020.164.7.050-058.

<sup>12</sup> See: *Chubukova S.G.* Legal Problems of Genetic Information Protection: Subjective Approach // *Vestnik of O.E. Kutafin University*. 2020. № 5. p. 97.







## 5. THE ROLE OF INTERNATIONAL LAW PRINCIPLES IN GENETIC TECHNOLOGIES

Currently, amid the advancement and integration of genetic technologies into human life within specific nations, international law lacks established general principles for regulating activities in this domain.

Are principles of international law, serving as foundational norms of human interaction, applicable to the international legal framework governing these matters? Specialists underscore the amplified significance of universally recognized principles and norms of international law amidst escalating complexities and crises in global relations. Thus, adherence to the letter and spirit of international law is indispensable in envisioning essential processes, including those within the Russian Federation<sup>13</sup>.

It is pertinent to consider certain doctrinal perspectives regarding the nature of general principles of international law.

In the field of international law, there exists no consensus regarding the content and legal nature of general principles of law, nor is there an unambiguous answer to whether they constitute sources of international law. Moreover, the term “general principles of law recognized by civilized nations” lacks an official interpretation. Currently, the term “international community” (community of nations) is often considered more appropriate<sup>14</sup>.

According to Y. S. Romashev, the definition of generally recognized principles of international law provided in Resolution No. 5 of the Plenum of the Supreme Court of the Russian Federation on October 10, 2003 “On the application by courts of general jurisdiction of universally recognized principles and norms of international law and international treaties of the Russian Federation”, is unduly restrictive, since the definition overlooks sectoral (specialized) generally recognized principles of international law, which may not possess preemptory status but nonetheless play a significant role in the context discussed in this article.

Furthermore, we will examine the relationship between preemptory norms of international law *jus cogens* and obligations *erga omnes* in order to identify a

<sup>13</sup> See: *Morozov A. N.* Constitutional reflection of universally recognized principles and norms of international law // *Journal of Russian Law*. 2018. № 7. p. 34.

<sup>14</sup> See: *Romashev Yu. S.* General principles of law in the system of international law // *Law. Journal of the Higher School of Economics*. 2021. № 3.





hypothetical possibility of elaboration of such principle(s) in the realm of modern genetic technologies for the collective security of human life.

The doctrine of international law lacks precise criteria for identifying norms as peremptory (*jus cogens*) and determining which obligations qualify as *erga omnes*. Generally, peremptory norms are norms that the international community considers impermissible to deviate from, whereas *erga omnes* obligations are obligations owed to the entire international community, encapsulating the substance of peremptory norms, as noted by S. V. Chernichenko<sup>15</sup>.

In our research framework, the notion holds significance in terms of the capacity, intention, and choice to unify diverse societies, including the international community, under a shared understanding of the necessity to introduce sectoral (special) principles in genetic technologies. These could include prohibitions on creating entities like designer babies, individuals with multivirus resistance, or “fearless warriors”.

G. I. Tunkin highlighted that acknowledging the existence of *jus cogens* reflects a paradigm shift in history’s new era<sup>16</sup>. This prompts the question: in the context of modern genetic technologies, does the international community and individuals alike require general principles as a shared understanding within this sphere of legal relations, akin to *erga omnes* characteristics?

S. V. Chernichenko underscores the fact that peremptory norms of international law and *erga omnes* obligations resonate with the current state of interstate relations. Key principles found in Articles 7 and 8 of the UN Charter<sup>17</sup> and the Declaration on Principles of International Law concerning friendly relations and cooperation between states are foundational. However, realizing these principles necessitates more specific treaty and customary norms, a longstanding truth<sup>18</sup> reiterated by S. V. Chernichenko.

Consideration of *subsidiary principles phenomenon* in the context of peremptory norms of international law is noteworthy. For instance, the principle prohibiting discrimination based on genetic heritage (Art. 11 of the Oviedo Convention) can be viewed as a contemporary specialized “extension” of the general principle of human

<sup>15</sup> See: *Chernichenko. S. B.* Interrelation of peremptory norms of international law (*jus cogens*) and obligations *erga omnes* // *Moscow Journal of International Law*. 2012. № 3. DOI. 10.24833/0869-0049-2012-3-3-17.

<sup>16</sup> Cited in: *S.V. Chernichenko*, op. cit. p. 7.

<sup>17</sup> Enacted by United Nations General Assembly resolution 2625 (XXV) of 24 October 1970.

<sup>18</sup> See: *Chernichenko S. V.* op. cit.





rights respect. In this context, can this specialized principle be recognized as surpassing its specific role to “attain” the status of an erga omnes obligation?

Furthermore, an exemplification of the contemporary evolution of the principle of equal rights and self-determination of peoples, as codified in the UN Charter and the Declaration, is pertinent. Considering the ambitious advancements in genetic technologies, such as the implementation of “human enhancement<sup>19</sup>” projects, a contentious issue arises regarding the reinterpretation of the principle of equality and self-determination of peoples. This occurs when segments of a population within a state or states may undergo “improvement” through DNA-editing technologies like CRISPR<sup>20</sup>. The question arises: What constitutes self-determination for individuals, given the implementation of principles prohibiting discrimination on genetic grounds and concepts of *genetic purity within nations*?

It is noteworthy that the principle of equal rights and self-determination of peoples stands at the forefront of contemporary international discourse as a fundamental principle of international law, originating in the post-colonial era and universally recognized in the 20th century<sup>21</sup>.

In light of the contemporary issue of developing and using new biological (molecular) weapons, it becomes crucial to reevaluate the foundational principles of international law. This includes the principles of non-use or threat of force, the right of states to self-defense in the event of a bio-attack, the principle of peaceful settlement of international disputes, and the principle of non-interference in the internal affairs of states. These principles present new challenges to both the theory and practice of international law, particularly with the emergence of new forms of sovereignty (such as biosovereignty, cyberbiosovereignty, and genomic sovereignty of states)<sup>22</sup> and new

<sup>19</sup> See, for example: *Buinyakova I. S.* Human enhancement biotechnology in the paradigm of transhumanist discourse // Scientific Vedomosti of Belgorod State University. Series: Philosophy, sociology, law. 2019. V. 44. № 2. p. 294-304; For and against human enhancement: the Higher School of Economics conducted a revision of the attitude to human enhancement. URL: <https://stratpro.hse.ru/human-success/news/789670169.html>; *Grebenshchikova E. G.* Human enhancement projects and the thesis of technological inevitability // Man. 2016. № 5. P. 30-39; Biotechnological human enhancement as a problem of socio-humanitarian knowledge: mater. School of young scientists / ed. by *B. G. Yudin, O. V. Popova*. M., 2017.

<sup>20</sup> See, for example: *Bogatyreva N. V., Sokolov A. Yu. M. et al.* Legal status of plants obtained using genome editing technology: prospects for Russia // Ecological Genetics. 2021. V. 19. № 1. p. 89-101; *Jewell K., Shankar Balakrishnan V.* Battle for the rights to CRISPR/Cas9 genome editing technology // WIPO Journal. 2017. April. URL: [https://www.wipo.int/wipo\\_magazine/ru/2017/02/article\\_0005.html](https://www.wipo.int/wipo_magazine/ru/2017/02/article_0005.html)

<sup>21</sup> See: *Morozov A.N.* op. cit. p. 35.

<sup>22</sup> See, for example: *Kalinichenko P. A., Nekoteneva M. V.* Genomic sovereignty of developing countries: priorities of legal regulation // Genetic technologies and law in the period of bioeconomy formation: a monograph / ed. by *Mokhov A. A., Sushkova O. V. M.*, 2020; *Tarasyants E. V.* International protection





types of international crimes (such as genocides). An interdisciplinary exploration is warranted into the principle of biological diversity across generations of humanity on Earth and current threats to its observance due to potential genetic modifications and alterations to human germ cells, constituting interference in the lives and health of future generations who have not consented.

## 6 BIOETHICS AND ITS ROLE IN INTERNATIONAL LAW: COMMON OBJECTIVES

Given the significance of this relationship, it is crucial to explore the shared goals and objectives between bioethics as a branch of international law and bioethics as an interdisciplinary field shaping the legal regulation of human activities involving genetic technologies.

*Bioethics* can be defined as a specialized form of social regulation, influenced partially by legal norms, aimed at defining approaches and measures for potential artificial interventions in human nature while preserving its fundamental essence. It facilitates the development of societal consensus on complex issues related to genetic research and fosters the formulation of social norms that may transition into legal regulations<sup>23</sup>.

The formation of bioethics as an interdisciplinary field is shaped by two primary factors<sup>24</sup>: 1) the rapid advancement of scientific and technological progress and its implications for human life and the rights of future generations; 2) the emergence of a framework of human rights in medicine and health during the 20th century, with subsequent challenges in realizing these rights through judicial protection.

According to the experts, a significant challenge in legal regulation within biomedicine is the presence of strong ethical self-regulation, highlighting the absence of universally recognized, clearly articulated documents containing fundamental

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and promotion of rights. V. International protection and promotion of human rights in the field of biomedical research. M., 2011; Rae G. Critiquing Sovereign Violence: Law, Biopolitics, Bio-juridicalism. Edinburgh, 2019; Richardson L. C., Connell N. D., Lewis S. M. et al. Cyberbiosecurity: A Call for Cooperation in a New Threat Landscape. URL: <https://www.frontiersin.org/articles/10.3389/fbioe.2019.00099/full>

<sup>23</sup> See: Law and Biomedicine ... p. 16-18.

<sup>24</sup> See, for example: Trikoz E., Gulyaeva E. Environmental cases of the ECtHR and the environmental risk of GMOs // E3S Web of Conferences. 2021. Vol. 244. Art. no. 12024. DOI: 10.1051/e3sconf/202124412024; Trikoz E. N., Gulyaeva E. E., Belyaev K. C. Russian experience of using digital technologies in law and legal risks of AI // E3S Web of Conferences. 2020. Vol. 224. Art. No. 03005. DOI: 10.1051/e3sconf/202022403005





principles and rules of bioethics specific to the field. To address this, a sensible balance between the two regulators is proposed involving law as a conservative, formal framework and ethics as a flexible counterpart that accommodates the significant role of self-regulation in healthcare governance<sup>25</sup>. This phenomenon is conceptualized in legal studies as the “symbiosis of law and ethics in medical practice”, which acknowledges the multidimensional and multisubjective nature of healthcare relations, not all of which can be inherently governed by legal norms alone<sup>26</sup>.

Currently, *bio-law* “genomic law” represents a specialized sub-branch of international law addressing several critical issues within modern genetic technologies. These include safeguarding human genetic identity, legal protections thereof, genetic testing protocols, the legal status of participants in genomic research (including genetic editing), the handling of genomic research results, the circulation of genetic data, the prohibition of genetic weapons, and related concerns.

Of particular significance are emerging or established sectoral principles shaping legal frameworks in the domain of modern genetic technologies.

Foremost among these is the *bioethical principle of justice*, intertwined with the classical maxim of “do no harm”, concerning unnecessary revelations about one's genome. It asserts that genetic information should not be utilized to harm or discriminate against individuals, families, or groups in clinical or non-clinical contexts, spanning employment, insurance, social integration, and overall well-being<sup>27</sup>. A comprehensive analysis of the 25 recommendations on ethical, legal, and social implications of genetic testing by the European Commission's Independent Expert Group in 2004 merits consideration in a separate study (Official Publications Department of the European Community, Luxembourg, 2004)<sup>28</sup>.

In the contemporary landscape of genetic technology, the *principle of genetic responsibility* assumes increasing importance. Ethical debates surrounding the protection of human rights and dignity in genetic research, organ, tissue, cell, and

<sup>25</sup> See: Law and Biomedicine ... p.15,19,28.

<sup>26</sup> See: *Putilo N. V.* Legislation of the Russian Federation on the protection of citizens' health: on the threshold of changes // Journal of Russian Law. 2010. № 10. p. 45.

<sup>27</sup> See more: *Furrow B., Greaney T., Johnson S.* et al. Bioethics: Health Care Law and Ethics (American Casebook Series). West Academic Publishing, 2013.

<sup>28</sup> In the literature there is an analysis of the report of the British Nuffield Council on Bioethics (Nuffield Council on Bioethics) on social and ethical problems of human genome editing 2018 on genetic engineering and human genome editing from the point of view of formation of international legal principles of regulation of these relations. See: *Pestrikova A. A.* Human genome editing: formation of international principles of legal regulation // Actual problems of Russian law. 2020. Vol. 15. № 2. p. 159-165. DOI: 10.17803/1994-1471.2020.111.2.159-165.





embryo transplantation, as well as the establishment of national and personalized biobanks, underscore the evolving concept of “genetic responsibility”. Rooted in collective societal attitudes towards future generations, its initial development dates back to discussions on genetic testing and the emergence of positive reproductive eugenics in the 1970s<sup>29</sup>.

The issue of collecting, processing, using, researching, storing, and transmitting genetic information pertaining to indigenous peoples and local communities worldwide, along with the subsequent application of this data in scientific research, warrants special attention in this study. On one hand, this practice significantly contributes to our understanding of human evolutionary history. However, it is crucial to recognize and subsequently incorporate into legal standard-setting processes that the collection, processing, use, and storage of such data carry a high potential for genetic discrimination.

Indigenous peoples, who represent the genetic diversity of nations and populations on Earth, also constitute a vulnerable group under international law, particularly concerning the protection of voluntary written consent for participation in genetic research and the safeguarding of their genetic data.

This underscores the importance of legally enshrining the protection of genetic information of indigenous peoples and local communities at both universal and regional levels<sup>30</sup>. Furthermore, it is essential to establish a prohibition on the development of racial and ethnic weapons targeting specific groups. Such a measure would help preserve the unique biocodes of the diverse nations and populations inhabiting the Earth<sup>31</sup>.

The study of the *concept of solidarity*, particularly in the context of ethical and legal biomedical debates, is important due to its correlation with the principle of patient autonomy and public solidarity. This issue was highlighted by the authors of the monograph “Law and Biomedicine” as a new vector for the development of legal

<sup>29</sup> See, e.g.: *Leefmann J., Schaper M., Schicktanz S.* The Concept of “Genetic Responsibility” and Its Meanings: A Systematic Review of Qualitative Medical Sociology Literature // *Frontiers in Sociology*. 2017. Vol. 1. Art. 18. P. 1—22. DOI: 10.3389/fsoc.2016.00018; *Genetic Responsibility: On Choosing Our Children’s Genes* / ed. by *M. Lipkin, P.T. Rowley*. New York, 1974. p. 93-100.

<sup>30</sup> See: *Danelyan A. A., Gulyaeva E. E.* Legal Regulation of Genomic Information Protection in the European Union (Part I) // *International Legal Courier*. URL: <http://inter-legal.ru/pravovoe-regulirovanie-ohrany-genomnoj-informatsii-v-evropejskom-soyuze-chast-i>.

<sup>31</sup> For further details, see, for example: *Gulyaeva E. E., Anisimov I. O.* The common heritage of mankind and the world heritage: correlation of concepts. *Suprema - Revista de Estudos Constitucionais*. 2022. Vol. 2. No. 2. p. 27-49. DOI: 10.53798/suprema.2022.v2.n2.a185





regulation of biomedical activities, including in connection with the constitutional reform in Russia in 2020<sup>32</sup>.

## 7 KEY INTERNATIONAL LEGAL FRAMEWORKS GOVERNING GENETIC TECHNOLOGIES

Article 1 of the 1997 Universal Declaration on the Human Genome and Human Rights states: “The human genome underlies the inherent commonality of all members of the human species and the recognition of their inherent dignity and diversity”. This international instrument guarantees respect for human rights and fundamental freedoms and freedom of research, emphasizing that a person's identity cannot be reduced to genetic characteristics and demands respect for their uniqueness. Article 6 of the Declaration enshrines the prohibition of discrimination based on genetic characteristics, and Article 7 obliges the protection, in accordance with the law, of the confidentiality of genetic data concerning human beings.

The preamble of the Oviedo Convention acknowledges the accelerated development of biology and medicine and underscores the necessity of respecting human beings both as individuals and as members of the human species, recognizing the importance of ensuring their dignity.

“The interests and welfare of the individual prevail over the interests of society or science” (Article 2 of the Oviedo Convention). This document is thus *human-centered*. “All medical interventions, including those for research purposes, must be carried out in accordance with professional requirements and standards” (Article 4 of the Oviedo Convention). “Any form of discrimination against a person based on their genetic heritage shall be prohibited” (Article 11 of the Oviedo Convention). “Interference in the human genome aimed at its modification may be carried out only for prophylactic, diagnostic, or therapeutic purposes and only on the condition that it is not aimed at modifying the genome of the heirs of a given person” (Art. 13 of the Oviedo Convention).

Thus, the international legal regulation of biomedicine primarily contains non-binding provisions, such as the principles and rules of bioethics. The proper legalization of these ethical norms involves transferring them to the level of national

<sup>32</sup> See: Law and Biomedicine ... p. 13.





legislation, exemplified by the “do good” principle enshrined in Article 2 of the Oviedo Convention.

## 8 LEGAL REGULATION OF GENETIC TECHNOLOGIES: INTERNATIONAL PERSPECTIVES

Experts have scrutinized the critical issue of inadequate legal regulation in the realm of genetic technologies, encompassing genetic research on human beings, transplantation of human organs and tissues, and cloning. N. B. Krysenkova and T. I. Chursina investigate the potential for harmonizing the advancement of biotechnologies with ethical standards and human interests through legal frameworks. They highlight that the legal regulation of these studies differs markedly across nations, in part due to the absence of standardized approaches to their organization, the establishment of systems for managing genetic research, and mechanisms for oversight of their conduct<sup>33</sup>.

The authors identify several models of legal regulation of genetic research in national legislation. One model entails the enactment of specific laws dedicated to regulating genetic research, as seen in Israel, Belgium, and Saudi Arabia. Another model relies on a compilation of legislative acts from various sectors of human life to address the nuances of genetic research. A crucial element in both models is obtaining consent for participation in research, which can be withdrawn at any time. Additionally, both models emphasize the regulation of biobanks, where national health authorities accredit their activities, oversee operations, and maintain a register. Another critical aspect involves establishing restrictions and special safeguards in national legislation for the collection, processing, and storage of genetic data (biological samples and donor data), including subsequent anonymization<sup>34</sup>.

The U.S. experience with relevant legal regulation is particularly noteworthy. The 1979 Belmont Report by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research outlines fundamental principles and recommendations that balance potential risks and anticipated benefits for both individuals and society, while upholding individuals' rights to freely choose their

<sup>33</sup> See: *Krysenkova N. B., Chursina T. I.* Legal regulation of genomic research in foreign countries // Journal of Foreign Legislation and Comparative Law. 2019. № 5. p. 141

<sup>34</sup> See: *Krysenkova N. B., Chursina T. I.* Legal regulation of genomic research in foreign countries // Journal of Foreign Legislation and Comparative Law. 2019. № 5, p. 152-153.







participation. Furthermore, the U.S. Genetic Information Nondiscrimination Act (GINA) of 2008 protects citizens from genetic discrimination in health insurance and employment<sup>35</sup>. For instance, the United States has distinct, specialized regulatory legal acts governing genetic research<sup>36</sup>.

In contrast, the legal regulation of genetic research in the People's Republic of China came under intense scrutiny following the controversial work of Chinese scientist He Jiankui. In the autumn of 2018, He announced the birth of the world's first "transgenic" children—twin girls genetically engineered using CRISPR/Cas9 technology to confer resistance to the HIV virus. In 2019, He was sentenced to three years in prison and fined for violating China's laws on human experimentation and performing medical procedures without a license.

This experiment sparked significant public, scientific, legal, and ethical controversy, not only in China but also globally. Concerns were raised about the unknown unintended genetic changes and potential mutations in the subsequent generations of these children. The WHO Advisory Committee on the Development of Global Standards for the Governance and Oversight of Human Genome Editing emphasized that conducting clinical trials of human germline genome editing technologies is currently irresponsible<sup>37</sup>.

In response, on May 28, 2019, China promulgated the Regulations on the Management of Human Genetic Resources to enhance the protection of human genetic information and ensure their legitimate use. Additionally, in 2003, China approved the Ethical Guidelines for Research in Human Embryonic Stem Cells, which established protocols for conducting such research<sup>38</sup>.

<sup>35</sup> Gulyaeva E. E. Peculiarities of Approaches to Legal Regulation of Biological Security in the United States and the People's Republic of China // Blog of experts of the Diplomatic Academy. 5 September 2023. URL: <https://www.dipacademy.ru/blog-ekspertov-diplomatcheskoj-akademii/avtory-bloga/gulyaeva-ee/osobennosti-podhodov-k-pravovomu-regulirovaniyu-obespecheniya-biologicheskoy-bezopasnosti-v-ssha-i-chnr/>.

<sup>36</sup> For more details see, for example: Lyutov N. L. Prohibition of genetic discrimination and protection of genetic personal data: prospects for modification of labour law norms // Journal of Russian Law. 2021. T. 25. № 10. C. 72-84. DOI: 10.12737/jrL202L124; Trikoz E. N., Mustafina-Bredikhina D. M., Gulyaeva E. E. Legal regulation of gene editing procedure: the experience of the USA and EU countries // Vestnik RUDN. Series: Legal Sciences. 2021. Vol. 25. № 1. p. 67-86. DOI: 10.22363/2313-2337-2021-25-1-67-86.

<sup>37</sup> WHO expert panel sets the stage for effective international control of human genome editing activities. Press Release, 19 March 2019. URL: <https://www.who.int/ru/news/item/19-03-2019-who-expert-panel-paves-way-for-strong-international-governance-on-human-genome-editing>

<sup>38</sup> See: Gulyaeva E. E. op. cit





## 9 CONTROVERSIAL LEGAL ISSUES IN GENETIC TECHNOLOGIES: A SUPREME COURT OF BRAZIL CASE STUDY

The debate over human rights in relation to human embryonic stem cell research continues, with contentious issues originating in the medical domain increasingly moving into the legal sphere and carrying significant ethical implications. This complex issue of defining embryos and germ cells as subjects of law has been addressed in the jurisprudence of the Brazilian Supreme Court.

The case in question is Direct Action No. 3.510-0 in Brazil (ADI, Ação Direta de Inconstitucionalidade / Direct Action of Unconstitutionality), which sought to declare Article 5 of Brazilian Law No. 11.105 of March 24, 2005, on Biosafety unconstitutional<sup>39</sup>. Article 5 of the Biosafety Law permits the use of stem cells derived from human embryos produced by in vitro fertilization through assisted reproduction for therapeutic and research purposes (ADI 3.510-0)<sup>40</sup>.

This case represents a notable example of national experience in Brazil, where the majority invoked key constitutional freedoms—such as the freedom of family planning, the freedom of scientific research, and academic freedom—alongside the dignity of the human person and the guarantees of the sanctity of life. The Supreme Court's decision highlights the intersection of legal, ethical, and scientific considerations in the context of genetic technologies.

It should be acknowledged that embryonic stem cell research aims to identify and potentially treat a variety of pathological diseases that significantly reduce human life expectancy, causing pain and suffering.

However, the contested provisions of Article 5 of the Brazilian Biosafety Law violate the fundamental principle of the inviolability of the right to life with regard to the human embryo, which is considered a form of human life. This jeopardizes human life

<sup>39</sup> See: *Miziara N. M.* Audiência pública e advocacia em saúde: o caso da ADI Nº 3.510-0. Public audience and health advocacy: the case of ADI Nº 3.510-0. URL: [www.stf.jus.br/portal/glossario/verVerbete.asp?letra=A&id=481](http://www.stf.jus.br/portal/glossario/verVerbete.asp?letra=A&id=481).

<sup>40</sup>For more details, see also: *Acero L.* Science, public policy and engagement: Debates on stem cell research in Brazil // *Genomics, Society and Policy*. 2010/11. Vol. 6. No. 3. p. 15-31; *Naara Luna.* From abortion to embryonic stem cell research: Biosociality and the constitution of subjects in the debate over human right // *Vibrant — Virtual Brazilian Anthropology*. 2015. Vol. 12. No. 1. DOI: [10.1590/1809-43412015v12n1p167](https://doi.org/10.1590/1809-43412015v12n1p167); *Luna N.* The right to life in context of abortion and stem cell research: disputes of religious agents and values in a Secular State (Brazil) // *Religiao & Sociedade*. 2013. Vol. 33. Iss. 1. DOI: [10.1590/S0100-85872013000100005](https://doi.org/10.1590/S0100-85872013000100005); *Travieso J.A., Ferraro A.V., Trikoz E.N., Gulyaeva E.E.* Bioethical Aspects of Human Rights in Modern Latin America // *Kutafin Law Review*, 2021. Vol. 8. No. 1. p. 85-98. DOI: [10.17803/2313-5395.2021.1.15.085-098](https://doi.org/10.17803/2313-5395.2021.1.15.085-098).





in its early stages and undermines a fundamental aspect of the legal system based on the protection and promotion of human dignity and respect for human rights in society.

In his judicial opinion, Judge-Rapporteur C. Ayres Britto addressed various aspects of the constitutional validity of the rules governing research in cellular or regenerative medicine, particularly the use of embryonic stem cells. He emphasized that Brazil's Biosafety Law establishes strict conditions for such research.

Judge Ayres Britto also stated that respect for the dignity of the human person is recognized as a fundamental principle, and the law aims to support efforts to restore the normal functioning of the organs and systems of the human body, thus improving the health and well-being of people suffering from various diseases. He further highlighted the importance of academic freedom, scientific research, and family planning, all of which are supported by the Brazilian Constitution.

Justice Ellen Gracie noted that there is no constitutional definition of the beginning moment of human life and that it is not the role of the Brazilian Supreme Court to establish concepts not explicitly or implicitly defined in the Constitution.

The question posed to the Brazilian Supreme Court in the case at hand was a legal question of interpretation of the Brazilian Constitution, on the right to the defense of life and human dignity. The task of the Court was to determine the conformity of Article 5 of Brazilian Law No. 11.105/2005 with the constitutional provisions in force.

Particular attention was given to the human characteristics of embryonic stem cells, highlighting the importance of principles such as necessity, integrity of genetic heritage, prior evaluation of potential positive results, and informed consent in research and treatment.

When considering the preservation of life on a broader scale, both nationally and globally, the "precautionary principle" becomes relevant. This principle currently underpins actions in environmental and public health fields and is supported by Articles 196 and 225 of the 1988 Brazilian Federal Constitution, although it is not explicitly articulated<sup>41</sup>.

The Brazilian Supreme Court faced a critical question: does the constitutional protection of life fully extend to embryos, particularly non-viable and cryopreserved embryos?

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<sup>41</sup> Supremo Tribunal Federal. ADI No. 3.510. Tribunal Pleno. Justice-Rapporteur Justice Carlos Britto, Judgment on March 5, 2008. DJe No. 96. URL: <https://redir.stf.jus.br/paginadorpub/paginador.jsp?docTP=AC&docID=611723>.





From a biological perspective, the germination of life includes not only the fertilization of the egg by the sperm but also viability, which is absent without what is understood as human pregnancy. This approach aims to give real meaning to the principle of human dignity and specifically supports the constitutional provisions recognizing the right to life and health as fundamental rights.

In this case, an interpreter devoid of religious considerations may adopt a perspective aligned with public interest, the social imperatives of scientific research, and the general welfare of society<sup>42</sup>.

Judge Gilmar Mendes notes that Brazilian Law No. 11.105, enacted on 24 March 2005, establishes safety standards and oversight mechanisms for activities related to genetically modified organisms (GMOs) and their derivatives. The preamble of the law articulates principles of protecting human life and health, precaution in environmental protection, and the promotion of scientific progress in biotechnology.

Article 5 of Brazilian Law No. 11.105 of 24 March 2005 is entirely devoted to regulating the use of embryonic stem cells extracted from human embryos obtained through in vitro fertilization for research purposes. The law carefully regulates several aspects, requiring that research be conducted only with non-viable human embryos, subject to parental consent and project approval by national ethics committees. The commercialization of the biological material used is strictly prohibited.

Gilmar Mendes emphasizes that Article 5 of the Brazilian Law in question should be interpreted to mandate that research and therapeutic procedures using embryonic stem cells derived from human embryos produced by in vitro fertilizations must be pre-approved and authorized by the Central Ethics and Research Committee of the Brazilian Ministry of Health.

According to the judgment of the Brazilian Supreme Court of Justice in the unconstitutionality claim (ADI No. 3.510-0), the 1988 Brazilian Federal Constitution does not explicitly define the beginning of human life or specify the exact moment it begins. Instead, the Constitution refrains from conferring distinct legal rights on individuals at various stages of life. Adopting the natalist theory, it emphasizes the significance of birth as the point at which legal rights and protections are granted,

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<sup>42</sup> Supremo Tribunal Federal. ADI No. 3.510. Tribunal Pleno. Justice-Rapporteur Justice Carlos Britto, Judgment on March 5, 2008. DJe No. 96.





thereby marking the commencement of legal existence and recognition of the individual within society.

Thus, within the natalist theory of individual legal personality, the right to life is tied to the moment of birth, and legal rights and protections extend to individuals from that point onwards. For instance, Article 2 of the 2002 Brazilian Civil Code states, “The civil legal personality of a person begins at birth, the moment life begins; however, the law protects the rights of the unborn from the moment of conception”.

The judgment of the Brazilian Supreme Court emphasized that the best interpretation of the provisions of the Brazilian Constitution is as follows: the concepts of “human rights and individual guarantees” pertain to the rights of a specific person—a real person who, from the moment of birth, becomes the holder of fundamental rights such as “the right to life, liberty, equality, security, and property”, along with other fundamental rights and guarantees like the right to health and family planning.

In conclusion, the Brazilian Supreme Federal Court clarified that stem cell research does not contravene the Brazilian Federal Constitution. The Constitution mandates that the State promote and stimulate scientific development and technological research (Art. 218) and ensure the right to health (Art. 196), and such research supports the realization of these rights. Additionally, the Court deliberately excluded religious considerations from the legal debate, focusing purely on constitutional principles and scientific advancement.

## 10. FINAL PROVISIONS

Research in genetic technologies, their related developments, and the application of their results have undeniably transcended the sovereign boundaries of individual states. Therefore, it is crucial that national and international principles and standards governing this field align to ensure cohesive legal regulation.

The Concept of Foreign Policy of the Russian Federation asserts that humanity is undergoing an era of revolutionary change, marked by the emergence of a multipolar world grounded on several key principles. These principles include the sovereign equality of states, respect for their right to choose development models, adherence to international law in regulating international relations, the rejection of double standards,





the indivisibility of security in global and regional contexts, and the diversity of cultures, civilizations, and social organization models<sup>43</sup>.

It is vital for humanity, as an international community composed of states, international organizations, and other stakeholders, to recognize the need to transition from “non-binding” and recommendatory norms in this area to unified, binding “*course-setting*” principles, some of which may attain the status of *erga omnes* obligations. This transition seems feasible after clearly delineating the boundaries of activities for participants in international legal relations, potentially leading to a balanced approach to the benefits and risks of genetic (genomic) technologies.

The rapid pace of advancements in genetic engineering, screening, testing, and other related technologies has outstripped the ability of legal frameworks at both national and international levels to respond adequately and promptly to the actualized interests of stakeholders. This discrepancy may be attributed to the phenomenon of *technological imperative*: humanity’s relentless pursuit of technological research, even in the face of existential threats.

Recognizing the importance of interests at all levels—from interpersonal and national to international and universal—is essential in the legal regulation of these relations. It is evident that the interests at stake have expanded beyond their initial focus on human health and quality of life within society<sup>44</sup>.

We posit that the current moment in international relations necessitates the establishment of effective working relationships between states and relevant international organizations, including the pursuit of mutual compromises. This approach will enable states to interact under current challenging conditions and collaboratively address intricate issues in the field of genetic technologies. In doing so, the foundation of international legal interaction naturally regains significance.

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<sup>43</sup> Presidential Decree No. 229 of 31 March 2023 "On Approval of the Concept of Foreign Policy of the Russian Federation".

<sup>44</sup> Thus, Presidential Decree No. 474 dated 21 July 2020, "On the National Development Goals of the Russian Federation for the Period Until 2030," includes the preservation of population, health, and well-being as one of its objectives.





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