



Genomic Protection in Brazil: A Multilevel Legal Approach

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Abstract

The development of biotechnologies, genetic research, and data-driven health applications has brought the human genome to the center of contemporary legal debates. In Brazil, the protection of the human genome does not derive from a single, comprehensive statute, but rather from a multilevel legal framework that combines constitutional guarantees, biosafety regulation, and personal data protection. This normative dispersion raises relevant questions concerning the coherence, scope, and effectiveness of genomic protection within the Brazilian legal system. This research, which sets out to analyze the legal regime applicable to genomic protection in Brazil, focuses on the interrelation of three foundational legal instruments: the 1988 Federal Constitution, the Biosafety Law (Law No. 11,105/2005), and the General Data Protection Law (Law No. 13,709/2018). The central purpose is to show that these different levels of regulation do not function in isolation, but rather converge in a coordinated manner to collectively establish the human genome as a legal value deserving of special protection and targeted normative attention connected to the imperatives of dignity, privacy and non-discriminatory treatment. The research was guided by the following question: to what extent does the convergence of constitutional principles, biosafety standards, and data protection regulations establish a cohesive legal model capable of safeguarding genomic integrity in Brazil, given the accelerating pace of biotechnology and the broadening reach of genetic data handling? The research sustains the hypothesis that, although fragmented, the Brazilian legal system establishes an integrated regime of genomic protection, in which constitutional principles serve as the normative foundation, the Law No. 11,105 of March 24, 2005 (Biosafety Law) imposes ethical and technical limits on genetic research, and the Law No. 13,709 of August 14, 2018 (General Data Protection) ensures informational self-determination and safeguards against misuse of genetic data. However, the absence of a unified statutory framework engenders interpretative challenges that demand systematic and teleological legal analysis.

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Защита генома в Бразилии: многоуровневый правовой подход

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Аннотация

Развитие биотехнологий, генетических исследований и медицинских приложений, основанных на данных, вывело геном человека в центр современных правовых дискуссий. В Бразилии защита генома человека не регулируется единым всеобъемлющим законом, а представляет собой многоуровневую правовую систему, которая объединяет конституционные гарантии, правила биобезопасности и защиту персональных данных. Такой нормативный разброс поднимает важные вопросы относительно согласованности, масштаба и эффективности защиты генома в рамках бразильской правовой системы.

Целью настоящего исследования является анализ правового режима, применимый к защите генома в Бразилии, путем изучения взаимодействия между Федеральной конституцией 1988 г., Законом № 11105 от 24.03.2005 (Закон о биобезопасности) и Законом № 13709 от 14.08.2018 (Общий закон о защите данных). Цель исследования — продемонстрировать, как эти нормативные уровни взаимодополняющим образом обеспечивают защиту генома человека как юридически защищенного интереса, связанного с достоинством, личностью, неприкосновенностью частной жизни и недискриминацией.

Основной исследовательский вопрос можно сформулировать следующим образом: в какой степени взаимосвязь между конституционными принципами, нормами биобезопасности и правилами защиты данных обеспечивает адекватную и согласованную основу для защиты генома человека в Бразилии, особенно в условиях научных инноваций и растущей обработки генетических данных? Этот во-

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прос отражает противоречие между технологическим прогрессом, научной свободой и необходимостью защиты основных прав.

На основе проведенного исследования сделан вывод о том, что, несмотря на фрагментарность, бразильская правовая система устанавливает интегрированный режим защиты генома, в котором конституционные принципы служат нормативной основой; Закон № 11105 от 24.03.2005 (Закон о биобезопасности) устанавливает этические и технические ограничения на генетические исследования, а Закон № 13709 от 14.08.2018 (Общий закон о защите данных) обеспечивает информационное самоопределение и гарантирует защиту от неправомерного использования генетических данных. Однако отсутствие единой законодательной базы порождает проблемы толкования, требующие систематического и телеологического правового анализа.

Ключевые слова: защита генома, геномная безопасность, персональные данные, право на жизнь, право на здоровье, генетические данные

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Introduction

From the latter half of the twentieth century, remarkable transformations have taken place in numerous branches of medicine and biology. The pace of progress in biomedical research continues to intensify; while its outcomes hold substantial promise for enriching and easing lives, they also provoke serious questions of fundamental rights and freedoms, even the very notion of human dignity. With such rapid advances in scientific and technological capability, the urgency of establishing sound legal protections for human rights within the biomedical domain grows ever more evident. Within this context, bioethics serves a vital purpose in bringing together the intellectual insights and perspectives of scholars and professionals from diverse disciplines to consolidate them into a systematic

ethical framework. In today's global setting, the regulation of human rights within the biomedical sphere requires two complementary approaches (Adamovsky, 2003): international and domestic. Without the norms and guidelines coordinated by international bodies, domestic legislative mechanisms enacted by sovereign states would lack a properly founded basis. While the legislation process requires a thorough consideration of the particularities in each jurisdiction, including gaps in material and institutional capacity, the heightened vulnerability of marginalized groups, as well as the asymmetric regional concentration of particular illnesses and health challenges, it is crucial that the connection between medical ethics and human rights be woven into all legal documents (Abashidze et al., 2009).

The biotechnological revolution of the 20th century has facilitated major discoveries, for instance, in the field of genetic engineering (Gazina et al., 2022). While new research in genetics is fundamental from a scientific perspective, it raises anthropological, moral, and other issues. From a legal perspective, advances in biomedical science directly impact the entire spectrum of human rights (especially natural or personal), as well as touching upon a relatively new group of human rights that is emerging in the fields of biomedicine and information technology (Andorno, 2002). The bioethical principles formulated within the discipline of bioethics, which emerged in response to the ethical and legal contradictions that have arisen over the course of implementing these rights, have been codified in various legal provisions (Bielov et al., 2021).

Implications for human rights that arose with changes to human life as a result of biotechnological progress (Song et al. 2021), which accelerated following the end of World War II, representing a turning point for human rights protection in general, were accompanied by changes in social values that were reflected in the development of bioethics. Bioethics is a multifaceted discipline that combines philosophy, morality, sociology, law, and other fields. The main challenges that arose during the inception of bioethics consisted in explaining the need for human physical well-being, ensuring human safety in the context of medical research, and, in general, responding promptly to biotechnological progress (Gulyaeva, 2022). As set out in the relevant legal documents, the most important principles underpinning bioethics are those concerning human dignity, autonomy, and voluntary informed consent

to any medical intervention (Bobrova et al., 2025). Due to their fundamental and guiding character, these principles became the basis for bans on illegal human experimentation (Price, 2000), human cloning, certain genetic research (Trikoz et al., 2025), along with other legal restrictions aimed at protecting human life and health (Farinella, Gulyaeva, 2024).

The scientific literature on biolaw offers some fascinating approaches to the concept of the common heritage of humanity. Against the backdrop of rapidly advancing genetic and genomic research, the idea of recognizing the human genome as a common heritage is gaining momentum. For instance, Professor Jean Buttigieg's recently published book, "The Human Genome as Common Heritage of Mankind", demonstrates the need to recognize the human genome as a common heritage of humanity as a legal principle of international law (Buttigieg, 2018). This is reflected in the growing need to establish independent international expert centers and commissions that will review the ethical and legal aspects of genomic research, as well as the confidentiality of information obtained from DNA samples, whether of indigenous peoples or local communities generally.

The need to develop a comprehensive system for the protection and promotion of human rights forms a necessary starting point for the legal regulation of biomedical ethics. In terms of its function as a normative social regulator, bioethics requires a legal architecture to govern social relations and guarantee the preservation of human rights. While bioethics in the legal field at the international level are generally couched in the form of recommendations that states should implement at their own discretion, this has not prevented the development of a consider-

able number of legal regulations informed by bioethics, which in turn require structuring and formalization into an independent branch of law, which is known as biolaw.

A characteristic feature of the subjective composition of biolaw is the inclusion of a specific type of legal entity: current and future generations of humanity (Trikoz, Gulyaeva, 2023). The granting of legal subject status to these entities is an ongoing debate in academic circles, particularly with regard to current and future generations. While references to such legal entities are frequently encountered in legal documents on bioethics, unlike legal persons, such legal entities are passive, i.e., beneficiaries.

A key element of biolaw is human biorights, which include somatic rights (rights to control one's body), rights aimed at protecting against environmental threats and human biological identity (a category of rights conditioned by the existence of threats to all humanity from viral infections), and rights aimed at ensuring humane treatment in connection with the development of biotechnology (the right to life, respect for human dignity, fair treatment, and informed voluntary consent). It is precisely around human biorights that the system and mechanisms of protection are built (Trikoz et al., 2024).

Constitution-based genome protections in Brazil

In the Brazilian constitutional legal code, the human genome is not the object of specific regulation (Gulyaeva et al., 2024). The Federal Constitution of 1988¹ neither establishes a distinct regime of genomic protection nor

directly regulates genetic research. Nevertheless, certain constitutional principles – particularly the protection of human dignity set forth in Article 1, inc. III – serve as general parameters for interpreting and applying statutory norms related to genetic research and genetic data. In this sense, dignity operates not as a source of specific prohibitions, but as a background criterion that informs the assessment whether scientific and technological practices involving genetic material are compatible with the protection of the human person as an end in itself.

This protection is reinforced by the constitutional safeguarding of interests relating to the individual person, as derived from Art. 5, inc. X, which guarantees the inviolability of intimacy, private life, honor, and image. The obtaining and communication of genetic information directly impacts these protected spheres due to its potential revelation of highly intimate biological characteristics and predispositions. The human genome therefore falls within the scope of constitutionally protected personal identity, requiring enhanced legal protection.

The constitutional right to privacy further substantiates genomic protection. In accordance with Art. 5, inc. X, the right to privacy extends beyond the simple protection of physical space or the inviolability of interpersonal communications to encompass an individual's authority over the personal and informational aspects of their identity. Considering their prognostic nature and heritability, and despite the absence of any explicit reference to this concept in the constitutional provisions, genetic data clearly

¹ Federal Constitution of 1988, Brazil. (1988, October 5). *Official Gazette of the Union*. Available at: http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm. (In Portuguese).

require constitutional interpretation in line with the principle of informational self-determination.

The guarantee of equality and the prohibition of discrimination embodied in the introductory part of Art. 5, inc. 1, serve as a vital shield against discriminatory practices based on genetic characteristics. The 1988 Brazilian Constitution prohibits every instance of differential treatment compromising the equal human dignity. The scope of this ban also captures discriminatory treatment by reason of biological or genetic properties in such sectors as professional employment, insurance coverage, and the accessibility of vital social services.

When read together, Articles 1 (inc. III) and 5 (introductory part and inc. X) lay down the constitutional groundwork for the protection of genomic rights in Brazil. The principles of human dignity, personality rights, the inviolability of privacy and non-discriminatory treatment merge into a single constitutional framework that guides and shapes the interpretation of both biosafety and data security statutes, bringing the protection of the genome to the level of a constitutional imperative rather than mere issues pertaining exclusively to the sphere of ordinary legislation.

The systemic and harmonizing function of constitutional principles within the Brazilian legal order ensures coherence among different normative layers to guide the interpretation of statutory law in contexts marked by scientific and technological complexity. Rather than operating as direct rules of conduct, these principles serve as interpretive stan-

dards that prevent normative fragmentation and orient the application of infra-constitutional norms toward the protection of fundamental values, particularly in areas where legislative regulation is sectoral or functionally differentiated (Alves, 2019).

Human life and health as the basis for biosafety regulation

The protection of human life and health constitutes the axiological and normative axis of the Law No. 11,105 of March 24, 2005 (Biosafety Law)². This orientation is explicitly affirmed at the outset of the statute. Article 1 establishes that the Law sets security standards and inspection mechanisms for activities involving genetically modified organisms “based on the guiding principles of the promotion of scientific advances (...) and the protection of human, animal and plant life and health”, combined with the observance of the precautionary principle. Human life and health are therefore not ancillary concerns, but primary legal interests that limit and condition genetic research.

This protective rationale is concretized through substantive prohibitions aimed at preventing irreversible harm to human biological integrity. Article 6, item III, categorically prohibits “genetic engineering on human germ cells, human zygotes, or human embryos”, thereby safeguarding not only the individual subject of research, but also future generations whose genetic constitution could be permanently altered. Article 6, item IV, further prohibits “human cloning”, reflecting a legislative judgment that such practices pose unacceptable risks to human

² Law No. 11,105, of March 24, 2005 (Biosafety Law). (2005, March 28). *Official Gazette of the Union*. Available at: http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/l11105.htm. (In Portuguese).

dignity, health, and the ethical foundations of biomedical research.

The same concern for the protection of human life and health underlies the conditional authorization set forth in Article 5, which provides that “for research and therapy purposes, the use of human embryonic stem cells obtained from human embryos produced by in vitro fertilization and not used in the respective procedure shall be permitted”, provided that specific conditions are met. According to the statute, such use is allowed when “they are unviable embryos” or when “they are embryos frozen three years or more on the date of publication of the Law, or, if already frozen on the date of publication of this Law, after completing three years counted from the date of freezing”. The provision further establishes that “in any case, the consent of the parents shall be necessary.” In addition, “research institutions and health services which carry out research or therapy with human embryonic stem cells shall submit their projects for assessment and approval to the respective research ethics committees.” Thus, the Law No. 11,105 of March 24, 2005 (Biosafety Law) expressly determines that “the commercialization of the biological material referred to in this Article shall be prohibited,” and that “its practice shall involve the crime characterized in Article 15 of Law No. 9,434, of February 4, 1997.”³

The protection within the Brazilian biosafety framework is further reinforced through

explicit criminal prohibitions directed at practices involving human genetic material. Article 24 classifies as a criminal offense the act of “using a human embryo in disagreement with the provisions of Article 5 of this Law,” imposing a “penalty of detention from one to three years, and a fine”. Article 25 criminalizes the conduct of “practicing genetic engineering in a human germ cell, human zygote, or human embryo”, subjecting the offender to “imprisonment from one to four years, and a fine”. Article 26, in turn, expressly prohibits “carrying out human cloning”, establishing a “penalty of imprisonment from two to five years, and a fine”.

By criminalizing the misuse of human embryos, genetic interventions in germ cells and embryos, and human cloning, the Law No. 11,105 of March 24, 2005 (Biosafety Law) draws non-negotiable legal boundaries around human genetic research. These penal provisions confirm that, in the context of the Brazilian legal order, activities that threaten the biological integrity of human life are not merely subject to ethical disapproval or administrative control, but are treated as serious violations of legally protected interests as substantive limits to scientific experimentation.

Privacy of genetic data and informational self-determination

The protection of the human genome in Brazil acquires a distinct and indirect le-

³ Law No. 9,434 of February 4, 1997 (Provides for the removal of organs, tissues and parts of the human body for transplantation and treatment purposes). (1997, February 05). *Official Gazette of the Union*. Available at: http://www.planalto.gov.br/ccivil_03/leis/l9434.htm. (In Portuguese). According to Article 15. Buying or selling tissues, organs, or parts of the human body: Penalty – imprisonment from three to eight years and a fine of 200 to 360 fine-days. Sole paragraph. The same penalty applies to anyone who promotes, intermediates, facilitates, or derives any advantage from the transaction.

gal dimension through the classification of genetic data as sensitive personal data under Law No. 13,709 of August 14, 2018 (General Data Protection Law). Unlike Law No. 11,105 of March 24, 2005 (Biosafety Law), which addresses genetic material from the perspective of scientific research and ethical limits on biological intervention, Law No. 13,709 of August 14, 2018 (General Data Protection Law) governs the informational use of genetic data, situating such information within the framework of fundamental rights, rights of the person, and informational self-determination. In this sense, the Brazilian General Data Protection Law does not regulate the human genome as a biological substratum, but conditions how genome-derived information may be collected, processed, and used in data-driven contexts. It is therefore essential to distinguish the human genome, understood as the biological foundation of human life and identity, from genetic data pertaining thereto, which correspond to information extracted from the genome once it is translated into data and linked to an identified or identifiable natural person.

Pursuant to Article 5, item II, the Law No. 13,709 of August 14, 2018 (General Data Protection) expressly defines genetic data as sensitive personal data, alongside biometric and health data, due to their heightened potential to generate risks of discrimination and violations of personal autonomy (Basan, 2025). By doing so, the legislator acknowledges that genetic information is not a neutral technical datum, but an element intrinsically linked to an individual's biological identity, hereditary traits, and potential health conditions. This legal classification produces immediate normative consequences: genetic data are subjected to a reinforced protection

regime that is stricter than those applicable to ordinary personal data, which regime is aimed at safeguarding the personality, privacy, and equality of the data subject. Such protection, however, operates exclusively at the informational level, constituting a functional and indirect form of genomic protection, without extending to the biological integrity of the genome or to genetic interventions themselves.

The legal regime governing the processing of genetic data is established not through an autonomous provision, but through the systematic application of Article 11, which regulates the processing of all sensitive personal data. Although Article 11 does not expressly mention genetic data, it fully applies to them insofar as they are expressly included within the category of sensitive personal data defined in Art. 5, inc. II. Article 11 is structured around a general rule of prohibition, under which the processing of sensitive data is allowed only in strictly defined and legally enumerated hypotheses. These include, first, the data subject's "specific and highlighted consent, for specific purposes" (Art. 11, inc. I); and, second, situations in which processing occurs without consent and is indispensable for purposes such as "compliance with a legal or regulatory obligation by the controller" (Art. 11, inc. II, al. "a"), "the conduct of studies by a research entity, with anonymization whenever possible" (Art. 11, inc. II, al. "c"), "the protection of the life or physical integrity of the data subject or of a third party" (Art. 11, inc. II, al. "e"), and "the protection of health", provided that the processing is carried out "exclusively by health professionals, health services, or sanitary authorities" (Art. 11, inc. II, al. "f", as amended) (Teffé, 2025).

The assumption behind this regulatory framework is that the processing of genetic

data carries significant risks. As such, the Brazilian General Data Protection Law does not rely on broad or open-ended permissions, but permits lawful data processing only where it is clearly necessary, and specifically purpose-bound, thus solidifying the notion of autonomous control over personal data. Applied to genomics, the principle guarantees the individual a real and operative say in how genome-derived information is collected, used, disclosed, and retained, given that irresponsible handling might violate a personal right, the repercussions of which are practically impossible to retract.

Closing observations

Global legal regulation of bioethics is still at a formative stage. Even so, the field is expanding through the adoption of normative instruments that give legal expression to a wide spectrum of human-rights guarantees within biomedical domains. However, such documents are currently insufficient to fully ensure the protection and promotion of human rights.

Universal regulation is distinguished by its broad scope and the large number of adopted documents on the protection and promotion of human rights in the field of bioethics. However, the question remains: how can soft legal norms effectively ensure the existence of a functioning system for the protection of human rights? It is likely that some norms will eventually become mandatory due to their established customary nature. However, in our opinion, it is too early to talk about this. There is also a need to establish a supervisory body that would monitor compliance with human rights and the implementation of legal norms and promptly respond to violations.

On the basis of the results of this study, we may now return to the research problem that guided the initial analysis: a consideration of whether the Brazilian legal system offers an adequate and coherent framework for the protection of the human genome without conflating its biological dimension with the informational regulation of genetic data. The investigation was driven by the concern that the increasing relevance of data-driven technologies could lead to conceptual imprecision, particularly by equating the protection of genetic data with the protection of the human genome itself.

Based on this problematization, the original research hypothesis can be formulated as follows: “Genomic protection in Brazil does not constitute a unified or autonomous legal regime, but rather results from a multilevel and functionally differentiated regulatory structure, in which constitutional principles, biosafety legislation, and data protection law address distinct dimensions of genomic vulnerability without overlapping their respective objects of protection”.

The analysis carried out throughout the research confirms this hypothesis. The constitutional framework, while not establishing a specific regime for genomic protection, provides general principles – such as human dignity, privacy, personality rights, equality, and non-discrimination – that function as interpretive parameters for statutory regulation. These principles do not directly regulate genetic research or genomic data, but guide the legitimacy and limits of legislative and regulatory choices in this field.

Brazilian constitutional protection of the genome is best understood through broad foundational principles rather than explicit constitutional rules. Given their superior

normative status, constitutional principles provide the main standards for evaluating the legitimacy and effectiveness of ordinary legislation. Where the Constitution offers no dedicated regulation of the human genome, these principles take on a systemic and integrative function, ensuring consistency of various statutory provisions in fields defined by the realities of scientific and technological advancement. Instead of imposing specific behavioral patterns, these principles act as referential standards for interpretation, which orient the application of infra-constitutional norms to constitutionally protected values, thus establishing the basis for differentiated regulatory structures governing biological safety and genomic information, respecting their normative identity.

From a biosafety perspective, Law No. 11,105 of 24 March 2005 establishes a set of firm boundaries around genetic research involving the human genome with the express objective of preserving human life and health. The statute does so through categorical limits, including the outlawing of human reproductive cloning, the prohibition of genetic engineering modification of germline material (germ cells, zygotes, and embryos), and the imposition of criminal liability for any use of human embryos beyond the circumstances clearly permitted by law.

Simultaneously, the law opens a narrow path for the use of embryonic stem cells, restricting it exclusively to research and therapeutic application provided that certain conditions are met: the embryos in question must be demonstrably non-viable or have been cryopreserved for an extended period, parental informed consent must be secured, and prior evaluation by a competent ethics committee must be obtained. In combina-

tion, these limits demonstrate a precautionary and forward-looking legislative approach, under which scientific research remains permissible, but is bounded by unambiguous legal protections designed to prevent lasting damage to biological nature of human beings, and to avert dangers that might cascade onto future descendants.

From the point of information regulation, Law No. 13,709/2018 (General Data Protection Law) operates on a separate normative level. In classifying genetic data as sensitive personal information and conditioning its processing on a strict restrictive mode, the statute refrains from the protection of the human genome in its quality as a biological matrix upon which human life is built, but instead regulates genetic information after it has been obtained from that biological source, recast as processable data, and traced to a particular or identifiable person. This normative structure gravitates toward the protection of the human personality, the right to privacy, and the principle of equality, seeking to avert discriminatory practices, surveillance-like profiling and breaches of personal autonomy connected to the misappropriation of genetic data. At the operational level, these protective measures find expression in a comprehensive ban on sensitive data processing, the stipulation that any authorized data handling must proceed from a clearly defined legal ground that includes the purpose restriction and necessity requirements, as well as the recognition of the individual's right to maintain oversight of, request access to, and formally challenge how their genetic data is used, most critically where automated systems are involved.

The results of this study clearly indicate that genome protection in Brazil has not de-

veloped into a cohesive or self-sufficient body of law. Instead, it functions as a stratified and functionally distinct regulatory arrangement. Within the constitutional framework, general principles do not in themselves provide specific rules for genetic science or genome data governance, but serve as interpretive guidelines that direct and constrain lower-level legislation, supporting coherence and normative validity of the regulatory system as a whole.

At the legislative level, biosafety laws regulate biological risks associated with genetic interventions, while data protection standards govern the use of information obtained from the genome. In recognizing that every level of regulation attends to a separate set of vulnerabilities and serves its own normative ends, this structural division reinforces

the conclusion that genetic data protection and the safeguarding of the human genome must not be treated as equivalent concerns.

The study thus validates the initial hypothesis to demonstrate that genomic protection in Brazil can function effectively only with the sustained clarity of conceptual and regulatory lines separating biological oversight from the governance of genetic information. The integrity of these boundaries constitutes the vital condition for legal unity and systemic soundness, simultaneously enabling a balance between scientific and technological progress and unconditional responsibility for preserving human life, personal dignity, and freedom of individual self-determination within a constitutional system bound by the primacy of law.

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