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Research involving humans in Brazil: a bioethical and historical perspective

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Abstract

This article analyzes the historical evolution of Brazilian ethical regulations on research involving humans, discussing the National Health Council Resolutions 1/1988, 196/1996, 466/2012 and 510/2016, in addition to Law 14,874/2024. It is a qualitative, document-based study with a historical-critical approach, comparing national regulatory frameworks with key international ethical research guidelines. Although the new law represents legal progress, significant criticisms remain, particularly regarding participant protection and the independence of research ethics committees. The study concludes that the new regulation requires adjustments to address gaps related to bureaucratization of processes and the autonomy of Brazilian ethical bodies. It recommends streamlining administrative procedures, strengthening the independence of research ethics committees and the National System of Research Ethics, and aligning Brazilian legislation with best international practices to ensure effective and continuous protection of research participants.

Keywords: Ethics, research. Ethics committees, research. Bioethics.

Resumo

Pesquisa envolvendo seres humanos no Brasil: perspectiva bioética e histórica

Este artigo analisa a evolução histórica das regulamentações éticas brasileiras sobre pesquisas envolvendo seres humanos, discutindo as Resoluções do Conselho Nacional de Saúde 1/1988, 196/1996, 466/2012, 510/2016 e a Lei 14.874/2024. Trata-se de pesquisa documental qualitativa com abordagem histórico-crítica, comparando os marcos regulatórios nacionais com as principais diretrizes internacionais de ética em pesquisa. Observa-se que, apesar do avanço jurídico trazido pela nova lei, persistem críticas significativas, especialmente quanto à proteção dos participantes e à independência dos comitês de ética em pesquisa. Conclui-se que a nova regulamentação necessita de ajustes para corrigir lacunas relacionadas à burocratização dos processos e à autonomia das instâncias éticas brasileiras. Recomenda-se simplificar procedimentos administrativos, fortalecer a independência dos comitês de ética em pesquisa e do Sistema Nacional de Ética em Pesquisa e alinhar a legislação brasileira às melhores práticas internacionais, assegurando, assim, proteção efetiva e contínua aos participantes de pesquisas.

Palavras-chave: Ética em pesquisa. Comitês de ética em pesquisa. Bioética.

Resumen

Investigacíon com seres humanos em Brasil: perspectiva bioética e histórica

Este artículo analiza la evolución histórica de la regulación ética brasileña en materia de investigación con seres humanos, discutiendo las Resoluciones del Consejo Nacional de Salud 1/1988, 196/1996, 466/2012, 510/2016 y la Ley 14874/2024. Es una investigación documental cualitativa con enfoque histórico-crítico, que compara estos marcos regulatorios con las principales directrices internacionales de ética en investigación. Aunque avanza jurídicamente la nueva ley, persisten críticas significativas sobre la protección de los participantes y la independencia de los comités de ética de la investigación. La nueva reglamentación requiere ajustes para corregir lagunas relacionadas con la burocratización de procesos y la autonomía de las instancias éticas brasileñas. Se recomienda simplificar los procedimientos administrativos, fortalecer la independencia de los comités de ética de la investigación y del Sistema Nacional de Ética en Investigación, y alinear la legislación brasileña con las mejores prácticas internacionales, para asegurar una protección efectiva y continua a los participantes de investigaciones.

Palabras-clave: Ética en investigación. Comités de ética en investigación. Bioética.

The authors declare no conflict of interest.

Research

Ethics in research involving humans is a fundamental component for conducting studies that respect and protect the dignity, integrity and rights of research participants [1]. Regulations governing research activities began to gain momentum in the early 20th century, in response to experiments involving vulnerable populations in studies of infectious diseases. In this context, the directive issued by the Prussian government in 1901—which regulated the participation of patients in medical experiments, with a focus on protecting vulnerable populations such as children in clinics and hospitals—stands as a historical milestone. This directive highlighted the need for strict oversight and for obtaining consent from individuals participating in scientific experimentation [2]. The debate on human experimentation grew in the following decades, with the consolidation of ethical principles aimed at protecting human dignity [3].

Since the atrocities committed during World War II, which led to the formulation of the Nuremberg Code in 1947, the international community has worked to establish guidelines that ensure the protection of individuals involved in scientific experimentation [4]. These efforts culminated in the creation of guidance documents for ethical research, such as the Declaration of Helsinki by the World Medical Association [5]; the Belmont Report by the United States government [6]; and the Guidelines of the Council for International Organizations of Medical Sciences (CIOMS), which, among others, provide ethical foundations for conducting research across various fields of knowledge [7].

Also in this context, it should be noted that a broader discussion on ethics in human research was prompted by Henry K. Beecher's seminal article, published in 1966 in the *New England Journal of Medicine* [8]. Beecher identified ethical shortcomings in several studies conducted in the US, revealing cases in which participants' safety and consent were not adequately respected, especially in clinical research. His article exposed the dangers of medical experimentation without proper ethical oversight, spurring a global movement to reform research standards.

In Brazil, bioethics applied to research involving humans started to develop in light of these international discussions, leading to the creation of national regulatory frameworks aimed at protecting research participants [9]. Thus, the evolution of ethical guidance for research with humans reflects a growing commitment by the Brazilian research community to safeguard participants and promote responsible and ethically sound scientific practices [10].

In this regard, the year 1988 stands out as both a historical and political milestone: first, due to the enactment of the Federal Constitution, known as the "Citizen Constitution," which established human dignity as a core principle and recognized fundamental human rights; and second, due to the publication, by the National Health Council (CNS) and the Ministry of Health, of Resolution 1/1988 [11]—the country's first resolution on research involving humans, which emphasized respect for the rights of research participants.

This resolution was later replaced by CNS Resolution 196/1996 [12], which also played a key role in strengthening and consolidating the principles and procedures for conducting ethically sound research in Brazil [12,13]. Another important regulation governing clinical research in the country was CNS Resolution 251/1997, which established specific guidelines for clinical trials of new drugs. It provided guidance on the development and evaluation of new substances, ensuring that clinical trials complied with both national and international ethical standards. Many of the issues addressed in CNS Resolution 251/1997 [14], such as the requirement for ensure informed consent and the protection of vulnerable groups, are revisited in Law 14,874/2024 [15].

The resolution was later reviewed, amended and replaced by CNS Resolution 466/2012 [16] and related regulations, which incorporated the scientific and technological advancements up to that point, while also reinforcing the importance of the informed consent process and the protection of vulnerable groups [17]. CNS Resolution 510/2016 [18] was introduced as a complement to Resolution 466/2012 [16-19], with the aim of addressing the specificities of research methodologies from the human and social sciences [20]. It recognizes the methodological diversity of these fields and adapts ethical procedures to better reflect their needs and challenges. Despite the criticisms and controversies surrounding its implementation, CNS Resolution 510/2016 [18] marked an important

step toward incorporating different scientific perspectives in the discussion on the adequacy of ethics in research involving humans [19].

Regarding Brazilian regulations, it is also important to highlight the role played by the National Health Surveillance Agency (ANVISA), created by Law 9,782/1999 [21], which, through its Collegiate Board Resolutions (RDC)—particularly RDC 9/2015 [22]—regulates the conduct of clinical trials with drugs in the country, among others. It is worth noting that ANVISA's RDCs are legally binding, unlike the CNS resolutions.

The enactment of Law 14,874/2024 [15] introduces significant changes to the regulatory framework governing research involving humans in Brazil. The first is carrying the force of law rather than serving as mere guidance like the CNS resolutions, which could not enforce mandatory procedures and principles for research involving human subjects. This new legislation institutes the National System of Ethics in Human Research and introduces new requirements and procedures for conducting such studies. However, it is noteworthy that the drafting and approval of the law were marked by intense debates and significant political conflicts, as well as pressure from various economic and academic sectors, particularly the pharmaceutical industry. This raised concerns about critical issues such as the autonomy of regulatory bodies and the potential negative impact on the protection of participants' rights.

In this article, we explore the historical evolution of Brazilian resolutions on research ethics, present a comparative overview of the similarities and differences between the CNS resolutions and the provisions of the new law, and offer recommendations based on international experiences for the improvement of research ethics in Brazil.

Method

This is a document-based study employing a qualitative approach and a historical-critical perspective. The analysis focuses on Brazilian resolutions related to research ethics involving human subjects, specifically CNS Resolutions 1/1988 [11], 196/1996 [12], 251/1997 [14], 466/2012 [16] and 510/2016 [18], in addition to the recent Law 14,874/2024 [15]. These documents were selected due to their historical relevance and their impact on the development of bioethical principles governing scientific experimentation with humans in Brazil. The comparative and critical analysis was guided by international benchmarks, particularly the Declaration of Helsinki [5], the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS) [7] and the Universal Declaration on Bioethics and Human Rights of the United Nations Educational, Scientific and Cultural Organization (UNESCO) [23]. The chosen approach was qualitative, with an emphasis on a historical-critical perspective, conducted through a comparative document-based analysis of Brazilian regulations and international recommendations. As this is a document-based study that did not involve the direct collection of data from human participants, ethical approval by a research ethics committee was not required.

Historical and Critical Review

International Context

Ethics in research involving humans traces its origins to historical events that underscored the need for robust guidelines to protect participants in scientific experimentation. One of the earliest milestones in human research regulation was the Prussian Code of 1901 [2], which establishing guidelines for medical experiments, focusing on the protection of vulnerable populations such as children, particularly in studies of infectious diseases. This pioneering regulation preceded the more well-known Nuremberg Code, developed in 1947 in response to the atrocities committed by Nazi doctors during World War II [24,25]. The Nuremberg Code consolidated ethical principles for experimentation, setting out ten essential guidelines, including voluntary consent from participants and the requirement of prior animal testing before applying new procedures to human subjects, with the goal of ensuring both the safety and ethical integrity of the studies [4].

The Declaration of Helsinki [5], first published in 1964 by the World Medical Association, expanded on these principles and became one of the most influential documents on research ethics involving humans [26]. The declaration stresses the importance of informed consent, ethical review by independent committees, and prioritizing participant well-being over the interests of science and society. Over the years, the Declaration of Helsinki has undergone several reviews to reflect scientific advances and changes in social and political contexts, remaining a cornerstone of international ethical standards for human research [27].

Another key document in this context is the Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the United States [6,28]. The report proposes three core principles for the ethical conduct of research involving human subjects: respect for persons, beneficence and justice [6]. These principles guide the ethical development of human research, ensuring that participants are treated with dignity and that the benefits and risks of studies are distributed fairly [6,29,30]. A significant precursor to the Belmont Report was Henry K. Beecher's 1966 article [8], which exposed ethical shortcomings in several US studies and revealed the extent to which research participants were being exposed to risks without proper consent. Beecher's findings [8,31] were instrumental in the development of the Belmont Report and the establishment of stricter ethical guidelines. The report also emphasizes the importance of informed consent and ongoing ethical review, and has recently been updated to address the new challenges posed by contemporary research ethics [30].

In addition to these frameworks, the International Ethical Guidelines for Health-related Research Involving Humans, developed by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), provide guidance for conducting research in different contexts, especially in developing countries [32]. One chapter of this guideline was written by the Brazilian Society of Tropical Medicine and the Brazilian Association of Anthropology, which, in 1986, published the Code of Health Rights for Communities, focusing on the protection of communities involved in research [33]. The CIOMS guidelines address issues such as equity in participant recruitment, protection of vulnerable populations and the need for independent ethical review of research protocols [34]. These guidelines complement and expand upon the principles established in the Declaration of Helsinki, adapting them to different cultural and socioeconomic contexts.

Another regulation is the Universal Declaration on Bioethics and Human Rights, adopted by UNESCO in 2005 [23], which expanded the traditional bioethical perspective by emphasizing human dignity, fundamental rights, social justice and equity. In Brazil, these principles are reflected—albeit partially—in CNS Resolutions 196/1996 [12], 466/2012 [16], and 510/2016 [18], and more recently in Law 14,874/2024 [15], especially with regard to the protection of vulnerable groups and the respect for the autonomy and dignity of research participants.

These international documents establish an essential benchmark for ethics in research involving humans, influencing the development of guidelines and regulations in various countries, including Brazil. Contextualizing the evolution of Brazil's research ethics regulations helps to clarify the country's progress and the challenges it faces in promoting responsible and ethically sound research practices.

National Context

In Brazil, the first formal regulation for research involving humans was CNS Resolution 1/1988 [11], which laid the groundwork for the creation of ethical standards in the country. Published shortly after the enactment of the Federal Constitution of 1988, it reflected the broader context of social and political reorganization, including the creation of the Unified Health System (SUS) and the National Health Surveillance Agency (ANVISA), as well as the recognition of fundamental and social rights.

CNS Resolution 1/1988 [11] introduced formal guidelines for research ethics in Brazil; however, it was limited in scope, relying on isolated

resolutions and lacking a more robust and integrated normative framework. From that initial step, research ethics regulation gradually evolved, culminating in resolutions such as CNS Resolution 196/1996 [13], which consolidated bioethical principles first introduced in 1988.

The creation of CNS Resolution 196/1996 [13] was driven by the growing recognition of the need for clear guidelines to protect research participants, in keeping with international developments in the field [13]. Inspired by documents such as the Nuremberg Code and the Declaration of Helsinki, CNS Resolution 196/1996 [13] aimed to align Brazil with global ethical standards, ensuring that scientific research respected the rights and dignity of its participants [13].

Among its main advances were the introduction of the concept of informed consent, the protection of vulnerable groups and the creation of the Research Ethics Committees (CEPs) [35]. These committees, composed of members from various fields of knowledge, remain responsible to this day for reviewing and approving research protocols, ensuring that studies are conducted in an ethically sound and responsible manner.

Nevertheless, it also faced criticism. Excessive bureaucracy was cited as an obstacle to conducting research, particularly in institutions with fewer resources. Additionally, the generalization of standards across different types of research and fields of knowledge was deemed inadequate, as it failed to take into account the methodological specificities of the human and social sciences. Also criticized was the lack of clarity in some terms and definitions, which led to varied and inconsistent interpretations among CEPs [36].

Another key research regulation in Brazil was CNS Resolution 251/1997 [14], which set specific guidelines for conducting clinical trials with new drugs. It marked a significant step forward by detailing procedures for pharmaceutical research, including requirements to ensure participant safety and transparency in clinical trial approval processes. The resolution established parameters for studies involving new substances, mandating ethical and rigorous evaluation of trials, and became a benchmark for clinical research regulation in Brazil.

CNS Resolution 466/2012 [16] was a necessary update to Resolution 196/1996 [12]. The background of its creation was marked by significant scientific and technological advances that required the revision of ethical guidelines to keep pace with the evolving realities of research [17]. Moreover, there was a recognized need to strengthen the protection of research participants and align Brazilian regulations with international best practices.

CNS Resolution 466/2012 [16] introduced several important advances, such as the inclusion of new terms (for example, "assent form," aimed at children, adolescents and judicially incompetent individuals) and a more detailed description of the process for obtaining informed consent, emphasizing the use of clear and accessible language. Another improvement was the strengthening of the CEPs, with a focus on their independence and the ongoing training of their members [37]. However, the resolution also faced criticism, such as overlapping evaluations, especially for multicenter studies, which had to be approved by both local CEPs and the National Research Ethics Commission (CONEP) [38]. This was seen as a barrier to the timely initiation of studies. Additionally, there were concerns about the pharmaceutical industry's influence on the formulation of standards, with fears that the new requirements might be considered a "regulatory bottleneck" that could reduce Brazil's competitiveness in international clinical trials.

Under development since 2008, Plataforma Brasil, an electronic system for the submission and monitoring of research, was operationalized and implemented with the publication of CNS Resolution 466/2012 [16-40]. The goal was to centralize and streamline the ethical review process, increasing transparency and efficiency. The resolution also reinforced the independence of the CEPs, ensuring they could operate autonomously and impartially, free from external interference that might compromise ethical evaluations.

CNS Resolution 510/2016 [18] was published in a context marked by intense and contentious debates over ethical regulation in the human and

social sciences [29]. As CNS Resolution 466/2012 [16] primarily addressed biomedical research, the need for specific guidelines for the human and social sciences became evident [19,41]. This led to disagreements between various academic groups and CONEP, reflecting tensions regarding the adequacy of ethical guidelines for the methodological particularities of these fields [42].

CNS Resolution 510/2016 [18] focused specifically on research in the human and social sciences, acknowledging the methodological diversity and the less interventionist nature of these fields [43]. It adapted ethical procedures to better reflect the practices of these disciplines, introducing specific terms and processes, such as "informed assent," and allowing consent to be given in different formats (written, audio or visual). However, it attracted considerable criticism. Researchers in these fields argued that, despite some progress, the resolution still failed to fully recognize the methodological and contextual specificities of human and social sciences. The ambiguity surrounding exemptions from CEP/CONEP review was also criticized, leading to inconsistent interpretations and variations in how CEP standards were applied.

CNS Resolution 510/2016 [18] was an important step toward aligning Brazil with global standards in the human and social sciences [19]. International guidelines, such as those set by the American Anthropological Association [44] and the British Sociological Association, [45] also emphasize the need for flexibility and the adaptation of ethical procedures to the specificities of the disciplines within the human and social sciences. However, it is essential to highlight the role of ANVISA in clinical research, especially in relation to drug trials, as the agency is responsible for assessing the safety, efficacy and quality of investigational drugs, ensuring that clinical trials comply with strict ethical and scientific standards. Its regulatory function is key to ensuring that trial results are reliable and that participants' rights are protected. Although these particularities are acknowledged, the methodologies and typologies mentioned were not described in the resolution, as they were to be addressed in future publications—which, to date, have not been issued.

Law 14,874/2024

Law 14,874/2024 [15], which regulates research involving humans and establishes the National System of Ethics in Human Research, was the result of a complex legislative process that began in 2015. It involved the drafting of initial proposals, public debates, hearings with experts and several reviews before the final text was approved. The aim of regulating research with humans through a law is to guarantee and protect the rights of research participants, as well as to ensure greater legal certainty in the relationships established in this context. The new regulation seeks to provide a solid legal foundation for conducting research, addressing the ethical and legal challenges that have emerged with the technological and scientific advances of recent decades.

The scientific and academic community reacted with mixed opinions to the drafting and enactment of the law. While some viewed it as a necessary step toward providing greater legal certainty for research involving humans, others raised concerns about several of its provisions. Criticisms focused on the potential loss of rights for research participants, the centralization of CONEP within the Department of Science, Technology and Strategic Inputs—which could compromise its independence—and the impact of the new rules on the bureaucratization and efficiency of ethical approval processes.

Chart 1 below compares the main aspects of CNS Resolutions 196/1996 [12], 466/2012 [16] and 510/2016 [18], as well as Law 14,874/2024 [15]. Their characteristics and criticisms are summarized in order to help compare and critically analyze the advances and challenges of ethical research regulation in Brazil.

The various resolutions and Law 14,874/2024 [15] reflect the ongoing and dynamic evolution of ethical principles and practices in research in Brazil. The law reaffirms the importance of informed consent, detailing the requirements for obtaining such consent and ensuring the protection of vulnerable groups. It also introduces specific guidelines regarding the use of placebos and the provision of follow-up care after clinical trials. However, there are concerns that the practical implementation of these regulations may be insufficient to fully guarantee the protection of the rights and well-being of participants.

Chart 1. Comparison of the main aspects of CNS Resolutions 196/1996, 466/2012, 510/2016 and Law 14,874/2024

Aspect	Resolution 196/1996 [12]	Resolution 466/2012 [16]	Resolution 510/2016 [18]	Law 14,874/2024 [15]
Rationale and basic principles	Principles of autonomy, non-maleficence, beneficence and justice	Updates principles and includes equity and human dignity	Focuses on the specificities of the human and social sciences	Introduces the National Research Ethics System; more detailed
Definitions and terms	Introduces basic terms such as "research" and "consent"	Introduces terms such as "assent form"	Introduces specific terms for the human and social sciences	Details terms such as "biobank" and "biorepository"
Ethical aspects	Informed consent, protection of vulnerable groups	Details consent and participant protection	Adapts ethical procedures for the human and social sciences	Maintains and elaborates on consent and protection processes
Research ethics committees	Creation and regulation of research ethics committees (REC)	Strengthens the independence and ongoing training of REC	Representation of members from the human and social sciences	Integrated structure and oversight by the National System
Informed consent process	Establishes basic requirements	Details the consent process and use of clear language	Adapts consent to the realities of the human and social sciences	Further details the consent process
Rights and protection of participants	Assistance and compensation in case of harm	Comprehensive assistance and enhanced data protection	Risk management and detailed protection for the human sciences	Care follow-up after clinical trials
Evaluation exemptions	Unspecified	Unspecified	Exemptions for specific kinds of opinion survey and public information	Defines specific exemptions and differentiated processes
National Research Ethics System	Unspecified	Unspecified	Complementary to CNS Resolution 466/2012	Creation of the National Research Ethics System
Deadlines and efficiency	Unspecified	Unspecified	Unspecified	Introduces specific deadlines for ethical review
Protection of participants	General protection	Reinforces privacy and confidentiality protection	Detailed protection for the human and social sciences	Robust protection and continuity of care
Responsibilities and training	Overall responsibility of the researcher and the institution	Reinforces ongoing training for REC members	Responsibility of researchers in the human sciences	Clear responsibilities and ongoing training
Criticism	Excessive bureaucracy; generalization of regulations; lack of clarity	Overlapping reviews; industry influence; overprotection	Lack of recognition of specificities; ambiguity in exemptions	Loss of rights; social control and independence; bureaucratization

Law 14,874/2024 [15] aligns with many aspects of international best practices, such as the CIOMS guidelines and the Declaration of Helsinki, but lacks effective mechanisms to ensure ongoing protection of participants following the conclusion of studies. In countries with more advanced regulations, such as the United States and European Union member states,

there is a stronger emphasis on transparency and accountability—areas that still need to be strengthened in the Brazilian law.

The law introduces guidance for post-trial care, but practical implementation of these provisions remains uncertain. Guaranteeing ongoing access to treatments can be crucial for participants who benefited during the research, preventing abrupt and potentially harmful interruptions.

A critical shortcoming of the Brazilian law is the lack of clarity regarding financial and logistical responsibility for post-study care. In jurisdictions with more robust regulations, such as the European Union, documents like EU Regulation 536/2014 on clinical trials [46] establish clear requirements that research sponsors are responsible for ensuring ongoing treatment after study completion. Similarly, in the US, FDA CFR Regulation 312.42 [47] requires sponsors to guarantee ongoing treatment in clinical trials where benefit to participants has been demonstrated. These examples highlight the need for Brazil to strengthen its provisions in this area.

Law 14,874/2024 [15] introduces specific deadlines for ethical review and appeal procedures aimed at increasing efficiency. However, excessive bureaucracy within research ethics committee reviews remains a significant obstacle. The centralization of processes may lead to delays, especially in emergency or strategic research.

The interpretation of the law and its future regulation should consider the Brazil's need to develop and become a hub for clinical research. As the country with the largest free and universal public health system in the world—the Unified Health System (SUS)—Brazil must invest in the development of innovative and accessible health technologies.

Final considerations

Ethics is essential to ensuring that scientific studies respect the dignity, rights and well-being of research participants. Ethically sound practices are key not only to protecting individuals but also to ensuring the integrity, trust and credibility of scientific research. The terminology used by the new law, "research with humans," differs from that previously adopted in resolutions, such as "research on humans." While research "on" humans suggests that the individuals themselves are the focus of the investigation, research "with" humans may involve studies in which humans are not the direct focus. The phrase "research involving humans" would be more comprehensive and appropriate, as it encompasses both studies directly focused on humans and those that use humans as participants in broader investigative contexts. The evolution of ethical research regulations in Brazil reflects an ongoing commitment to these principles, although significant room for improvement remains.

This article reviewed the evolution of ethical research regulations in Brazil, from CNS Resolution 1/1988 [11] to Law 14,874/2024 [15]. CNS Resolution 1/1988 [11] was groundbreaking in establishing broader guidelines for protecting research participants, introducing fundamental principles that included a wide range of studies and topics, and setting the first regulatory frameworks for conducting research in Brazil. CNS Resolution 196/1996 consolidated these principles by creating the CEPs and formalizing mechanisms for ethical protection. CNS Resolution 466/2012 [16] updated and expanded these principles, reinforcing the need for informed consent and integrating technological advances such as Plataforma Brasil. Despite being complementary, CNS Resolution 510/2016 [18] focused on the particularities of the human and social sciences, adapting ethical procedures to those fields.

Law 14,874/2024 [15] consolidated and expanded these guidelines. However, it also attracted criticism regarding the protection of participants' rights, the independence of oversight bodies and bureaucratization of processes.

Recommendations for improving ethical practices and policies in research in Brazil include:

- Strengthening the independence of the CEPs and CONEP: ensuring that the CEPs and the National System of Ethics in Human Research operate free from political and economic influences, especially those from the pharmaceutical industry. This can be achieved through governance mechanisms that guarantee the autonomy of these institutions.

- Streamlining administrative processes: reducing bureaucracy without compromising participant protection. This may include implementing more efficient electronic systems for submitting and reviewing protocols, as well as establishing clearer and more reasonable deadlines for ethical and methodological evaluation of research protocols.
- Guaranteeing post-study access: establishing clear rules regarding financial and logistical responsibility for continuing follow-up after studies, ensuring participants continue to receive appropriate care.
- Ongoing training of CEP members: providing CEP members with continuous professional development to ensure they stay abreast of the latest scientific and ethical advances. This includes participation in workshops, courses and national and international conferences.
- Adopting international standards: harmonizing Brazilian regulations with international standards such as the CIOMS guidelines, the Declaration of Helsinki and Good Clinical Practice to ensure Brazil maintains its competitiveness and integrity in the global research arena. It should be noted that the new law does not prevent adopting these standards; rather, it provides a framework for their effective implementation. It is also important to highlight the role played by ANVISA, one of only five health surveillance agencies worldwide that are part of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Management Committee, reinforcing Brazil's commitment to the highest international standards in clinical trials.

In conclusion, the enactment of a law aimed primarily at guiding and regulating research involving humans in Brazil highlights the importance of the subject and its context. However, many challenges remain, such as the interpretation and regulation of Law 14,874/2024 [15] regarding respect for human rights, fundamental rights and social rights, particularly the right to health and access to innovative health technologies for all Brazilians.

Thus, research involving humans, considering Brazil's particularities and characteristics, should take into account not only the national regulatory framework but also international experiences and international law in planning management models, good practices and policies for the evaluation of research projects. The most important aspect in this context, however, is not to lose sight of the key goal: ensuring, respecting and protecting the rights of research participants.

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