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Informed consent under debate: Impacts of Law No. 14.874/2024

Consentimento informado em debate: impactos da Lei nº 14.874/2024

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ABSTRACT

Introduction: The enactment of Law No. 14,874/2024 marks a historic milestone in the regulation of clinical research in Brazil, granting the force of law to ethical principles previously established only through resolutions. This transformation aims to provide greater legal certainty and expedite regulatory processes while posing new challenges to the protection and autonomy of research participants. Objective: This manuscript aimed to critically examine the regulatory framework established by Law No. 14,874/2024, with a focus on its impact on the process of obtaining the Informed Consent Form (ICF) in clinical research conducted in Brazil. Method: It offered a normative and critical analysis of the new legal structure in light of previous national guidelines and international ethical standards, with the purpose of identifying institutional advancements, operational risks, and implementation gaps that directly affect the protection of research participants. Results: The new legislation consolidates and replaces historic regulations, such as CNS Resolutions No. 196/1996 and No. 466/2012, by granting greater legal force to ethical guidelines and introducing mechanisms for the centralization of ethical review, reduction of bureaucratic barriers, and acceleration of regulatory procedures. Conclusion: Despite these advances, which may increase the country's attractiveness for clinical trials, significant challenges remain, particularly regarding the effectiveness of the ICF in light of Brazil's regional, educational, and sociocultural inequalities. The original contribution of this study lies in its critical reflection on the potential disconnect between the normative assumptions of Law No. 14,874/2024 and the actual conditions for ICF comprehension by research participants. By doing so, the manuscript seeks to address a gap still scarcely explored in the literature: the ethical effectiveness of the new law in terms of communication, autonomy, and justice in participant recruitment and informed consent across diverse and vulnerable contexts.

KEYWORDS: Clinical Trial; Drug Regulation; Health Surveillance; Research Ethics; Informed Consent Form; Drugs

RESUMO

Introdução: A promulgação da Lei nº 14.874/2024 representa um marco histórico na regulação da pesquisa clínica no Brasil, conferindo força de lei a princípios éticos anteriormente estabelecidos apenas por resoluções. Essa transformação busca oferecer maior segurança jurídica e celeridade aos processos regulatórios, ao mesmo tempo em que impõe novos desafios à proteção e à autonomia dos participantes de pesquisa. Objetivo: Analisar criticamente o marco regulatório estabelecido pela Lei nº 14.874/2024, com ênfase em seus efeitos sobre o processo de obtenção do Termo de Consentimento Livre e Esclarecido (TCLE) em pesquisas clínicas realizadas no Brasil. Método: Trata-se de uma análise normativa e crítica do novo arcabouço legal conduzida por meio de uma revisão narrativa da literatura à luz das diretrizes nacionais anteriores e de parâmetros éticos internacionais, com o propósito de identificar avanços institucionais, riscos operacionais e lacunas de aplicação que impactam diretamente a proteção dos participantes. Resultados:

A nova legislação consolida e substitui normativas históricas, como as Resoluções CNS nº 196/1996 e nº 466/2012, conferindo maior força jurídica às diretrizes éticas e introduzindo dispositivos para a centralização da análise ética, redução da burocracia e agilidade da tramitação regulatória. Conclusões: Apesar desses avanços, que podem ampliar a atratividade do país para pesquisas clínicas, persistem desafios importantes – sobretudo no que diz respeito à efetividade do TCLE diante das desigualdades regionais, educacionais e socioculturais da população brasileira. A contribuição inédita deste estudo reside na problematização do possível descompasso entre os pressupostos normativos da Lei nº 14.874/2024 e as condições reais de compreensão do TCLE por parte dos participantes. Ao fazê-lo, o manuscrito busca preencher uma lacuna ainda pouco explorada na literatura: a análise crítica da efetividade ética da nova legislação no plano da comunicação, da autonomia e da justiça no recrutamento e no consentimento em contextos diversos e vulneráveis.

PALAVRAS-CHAVE: Ensaio Clínico; Legislação de Medicamentos; Vigilância Sanitária; Ética em Pesquisa; Termo de Consentimento Livre e Esclarecido; Medicamentos

INTRODUCTION

The enactment of Law No. 14,874, dated May 28, 2024, marks a turning point in the regulatory trajectory of clinical research in Brazil, responding to a long-standing demand from the sector for greater legal certainty, predictability, and speed in ethical and administrative procedures. Since the 1990s, this field has been regulated by sub-statutory regulations, such as National Health Council (CNS) Resolution No. 196, dated October 10, 1996, which established the Research Ethics Committee (REC) and National Research Ethics Commission (CONEP) system, and subsequently by CNS Resolution No. 466, dated December 12, 2012, which reinforced the principles of respect for dignity, autonomy, and the protection of vulnerable groups. Despite their normative importance and their structuring role, these resolutions lacked the force of law, which frequently led to legal uncertainty, interpretive inconsistencies, and jurisdictional disputes.

The main distinction between resolutions and laws lies precisely in their normative power: while resolutions are issued by collegiate bodies and serve as guidelines, federal legislation is drafted by the National Congress, has binding force, and unequivocally applies to all parties involved[1]. With the entry into force of Law No. 14,874/2024, a robust legal framework is thus established, capable of standardizing procedures, reducing disputes, and ensuring greater stability in regulatory decisions. In practice, this means less room for divergent interpretations and greater clarity regarding institutional responsibilities, which is particularly relevant in a field as sensitive as research ethics involving human subjects.

This regulatory transformation brings Brazil into closer alignment with internationally established regulatory models, such as those observed in the European Union and the United States, benefiting not only the local research environment but also the country's participation in multicenter consortia and large-scale studies. At the same time, it poses new challenges: the conversion of established ethical principles into legal provisions requires caution and constant critical vigilance so that the formalization of ethics does not result in its bureaucratization.

In light of this scenario, this study aimed to critically analyze the effects of Law No. 14,874/2024 on the process of obtaining and understanding the Informed Consent Form (ICF) in clinical research conducted in Brazil.

METHOD

This study adopts a normative and critical review to examine the impacts of Law No. 14,874/2024 on the process of obtaining the Informed Consent Form (ICF) in clinical research in Brazil. The analysis was conducted considering prior national guidelines and international ethical standards, encompassing regulatory documents, normative frameworks, and scientific publications addressing informed consent, research ethics, and the regulation of clinical studies. The method consisted of a critical interpretation of these instruments, seeking to identify advances, risks, and operational gaps relevant to the Brazilian context.

A narrative literature review was conducted, appropriate to the exploratory nature of the study, covering official documents (national and international laws, resolutions, and guidelines) through direct consultation of repositories and official websites (particularly those of the Brazilian Health Regulatory Agency—Anvisa, the Ministry of Health, and the National Health Council—CNS), as well as scientific articles published in specialized journals. Sources were selected based on thematic relevance, prioritizing materials that discuss ethical, legal, and operational aspects of the ICF and the regulation of clinical research. Keywords related to "informed consent," "research ethics," "clinical research regulation," and "Law No. 14,874/2024" were used, with searches conducted in databases such as the Scientific Electronic Library Online (SciELO) and PubMed.

A targeted and deliberately restricted search was then conducted to identify manuscripts whose central focus was the ICF in its ethical, legal, and operational dimensions, including publications in Portuguese, English, and Spanish. The initial search retrieved 112 records, which underwent deduplication and screening based on titles, abstracts, and subsequent full-text reading, applying as a relevance criterion that ICF constitutes the main object of analysis or that the text explicitly addresses ethical, legal, or operational aspects of the research consent process. Strictly empirical studies without normative discussion and documents without a full text available were excluded.

In line with the objective of a normative and critical review, which prioritizes sources of high analytical density, 14 articles were deemed suitable for final inclusion. Concurrently, a

targeted survey was conducted in official institutional repositories (Anvisa, Ministry of Health, and CNS) to identify normative and guiding acts such as laws, Collegiate Board Resolutions (RDC), normative instructions, administrative orders, and technical notes, selected when their applicability directly pertained to content, formal requirements, protection of vulnerable populations, and/or procedures for submission and ethical review, all of which were integrated into the critical analysis as normative references.

No strict time frame was established, as the analysis required the incorporation of both fundamental historical documents (e.g., the Nuremberg Code, the Declaration of Helsinki) and recent texts, including Law No. 14,874/2024 itself. The selection considered criteria of relevance and alignment with the study's objectives. The information was processed through a critical and interpretive analysis, comparing the new legal framework with previous regulations, as well as assessing its compatibility with international ethical standards.

RESULTS AND DISCUSSION

New Legal Framework

The enactment of Law No. 14,874/2024 constitutes a legal milestone of great significance in the regulation of clinical research in Brazil, as it consolidates and transforms guidelines previously established by resolutions into legally binding obligations. Among the innovations introduced, the creation of the National System of Ethics in Research Involving Human Subjects (SINEP) stands out; this regulatory framework centralizes the coordination of the national ethics system, defines clear responsibilities among the involved bodies, and establishes legal deadlines for the evaluation of protocols by ANVISA and the Ethics Committees (RECs).

The new national ethics body, within the scope of SINEP, assumes strategic functions: drafting complementary regulations, accrediting and overseeing RECs, monitoring the system's effectiveness, and providing ongoing training for its members. Additionally, it acts as an appeals body in cases of disagreement between researchers and RECs, strengthening the legal certainty of decision-making processes.

Another significant advancement concerns the centralization of ethical review in multicenter studies, allowing a single REC to conduct an ethical review valid for all participating centers. This measure aims to reduce duplication of reviews and harmonize opinions, contributing to greater regulatory efficiency. At the same time, the requirement that higher-risk research be evaluated exclusively by previously accredited Research Ethics Committees (RECs) introduces a new level of qualification and accountability, raising the standard of ethical scrutiny for potentially more complex and sensitive studies.

Additionally, the legislation includes provisions aimed at ensuring equity in ethical review, particularly for research involving special populations, by requiring the inclusion, whenever possible, of representatives from the directly involved population groups and of consultants familiar with their sociocultural contexts. This provision seeks to ensure a more context-specific ethical review, sensitive to the linguistic, cultural, and traditional specificities of the participating communities—in line with international principles of justice and respect for diversity.

The expected impacts of this new regulatory framework include streamlining submission and review processes, increasing regulatory predictability, and strengthening Brazil's position as an attractive and ethical environment for the development and conduct of clinical research by reducing bureaucracy and providing greater legal certainty to researchers and sponsors[2].

These changes aim not only to increase the efficiency of research processes but also to strengthen participant protection, ensuring that research is conducted ethically and transparently, in line with international best practices in clinical research.

However, while these structural advances are promising, they require attention regarding their effective implementation, especially regarding the concrete protection of participants.

Considering these aspects, some of the changes introduced by the new law directly impact the informed consent process, requiring a thorough analysis of their implications for everyday ethical practice.

Challenges to informed consent raised by the law

Law No. 14,874/2024 constitutes an important regulatory advance by promoting greater speed in regulatory processes and formally aligning Brazilian clinical research with international standards of ethical governance. However, the effectiveness of this legislation regarding the protection of participants—especially in the informed consent process—depends on its ability to address the country's structural inequalities. Regional, cultural, and educational diversities, language barriers, and social vulnerabilities are factors that, if not properly addressed, can undermine the substantive content of the ICF, reducing it to a mere procedural formality.

The promise of robust ethical protection, implicit in the provisions of the new law, requires more than normative standardization: it demands concrete strategies to ensure the intelligibility of consent in real, diverse contexts that are often marked by low health literacy. The central ethical challenge lies, therefore, in ensuring that consent is not only free in legal terms but truly informed in cognitive and relational terms—an essential condition for the legitimacy of research involving human subjects.

This article proposes a critical analysis of the implications of Law No. 14,874/2024 on the informed consent process, with an emphasis on the tensions between the structural advances of the legislation and the persistent obstacles to its equitable application. By examining the effects of the new legal provisions on the clarity, accessibility, and effectiveness of the ICF,

the study seeks to contribute to the regulatory debate by highlighting the need for complementary mechanisms to ensure that ethical protection is truly achieved, especially among the most vulnerable groups.

Literature Review

History of the ICF

The ICF is a cornerstone of the ethical standards governing clinical research both in Brazil and internationally and is essential for ensuring that participants are properly informed about the risks, benefits, and rights involved in their participation in a study[3]. Its origins date back to global and regional guidelines established throughout the 20th century in response to unethical practices in human experimentation, such as the Nuremberg Code (1947) and the Declaration of Helsinki (1964).

The requirement for informed consent safeguards the autonomy of research subjects, protecting their dignity and integrity, and serves as a fundamental mechanism for promoting transparency and ethical accountability in scientific research involving human subjects[4]. Consolidated through international regulatory frameworks such as the Nuremberg Code and the Declaration of Helsinki, the ICF reflects a commitment to responsible scientific practices, particularly in response to historical abuses committed in the name of science[5,6].

In Brazil, the ICF was initially regulated by CNS Resolution No. 196/1996, which established informed consent as a mandatory requirement for all research involving human subjects. This document was subsequently revoked by CNS Resolution No. 466/2012, which reiterated the ethical principles of respect for human dignity, protection of participants, and promotion of their autonomy[7].

CNS Resolution No. 466/2012 emphasized that the informed consent form must be clear, accessible, and understandable to all participants, and that researchers have a responsibility to ensure that consent is obtained freely, without coercion or undue influence. The resolution also addressed important aspects related to the protection of vulnerable groups, such as children, the elderly, and people with disabilities, stipulating that consent must be adapted to meet the specific needs of these groups. In addition, CNS Resolution No. 510, dated April 7, 2016, specified the ethical requirements for research in the social sciences and humanities, reinforcing the importance of consent in studies involving human subjects in less clinical but equally sensitive contexts[8].

These legal frameworks were inspired by the International Guidelines on Good Clinical Practice (ICH-GCP), adopted globally as a quality standard for conducting clinical research. The ICH-GCP guidelines emphasize that the ICF is a document that ensures the protection of participants' rights, safety, and well-being, in addition to guaranteeing that studies are conducted ethically and in compliance with international regulatory standards[4].

Global Impact and Local Practices

On the international stage, informed consent has become an essential practice in clinical research, regulated by global documents such as the Nuremberg Code and the Declaration of Helsinki, in addition to the ICH-GCP. These documents define researchers' obligation to ensure that all participants fully understand the risks and benefits of a study before consenting to participate.

Historical studies, such as the Tuskegee Study in the United States (1932–1972), in which African American men were deliberately denied treatment for syphilis, illustrate the dangers of unethical practices and the importance of informed consent in preventing the recurrence of such atrocities[9]. Other examples, such as the Willowbrook Study (1956–1970), in which children with intellectual disabilities were intentionally infected with hepatitis to study the disease, and the Cincinnati Radiation Experiment (1960–1971), in which cancer patients were exposed to high levels of radiation without their knowledge, reinforce the crucial role of ICF as a safeguard against the exploitation of participants[10,11].

Although grounded in established international guidelines, informed consent practices in Brazil face structural challenges related to the profound social, educational, and territorial inequalities that characterize the country. Law No. 14,874/2024, by seeking to reduce bureaucracy in processes, expedite the approval of studies, and strengthen legal certainty for researchers and sponsors, represents progress at the regulatory level[2]. However, its ethical effectiveness will depend on the ability to recognize and accommodate the heterogeneity of local contexts—especially in multicenter studies with unified ethical reviews.

It is essential that the process of drafting, submitting, and obtaining the ICF be sensitive to participants' linguistic, cultural, and cognitive barriers. The formal standardization of documents and procedures must not obscure the need for adaptive strategies, at the risk of compromising the principle of autonomy and reducing consent to a merely formal act. Thus, regulatory harmonization will only be ethically and operationally robust if accompanied by mechanisms that ensure the intelligibility of the ICF in the different territories where the research will be conducted.

Recent studies

Recent studies on the regulation of informed consent in various countries highlight how different legislations have adapted to enhance the protection of research participants. For example, in the United Kingdom, the implementation of *Regulation* (EU) 2017/745 on medical devices introduced significant changes in how consent is obtained and processed, with a particular focus on transparency and communication with participants[12]. In Australia, the Australian Human Research Ethics Guidelines revised consent practices, especially for vulnerable groups, increasing requirements

to ensure that Indigenous and rural populations have a full understanding of their participation[13].

In the Brazilian context, the enactment of Law No. 14,874/2024 introduces provisions that have the potential to significantly transform the process of obtaining informed consent. By seeking to streamline regulatory procedures and promote alignment with international ethical standards, the legislation responds to longstanding demands from the field of clinical research. However, its practical effectiveness will depend on how these guidelines are implemented in the face of the country's persistent challenges, such as high rates of low educational attainment, unequal access to information, and linguistic and cultural barriers that affect large segments of the population[2].

These tensions highlight that, although regulatory advances are significant, important gaps remain between the consent envisioned by the standards and the consent that is feasible under the concrete conditions of many research settings. For the ICF to be truly free, informed, and accessible, in line with bioethical principles and the commitments made by Brazil in international forums, it is essential to adopt more inclusive communication approaches, strategies adapted to different levels of health literacy, and tools that allow for the systematic and ethical assessment of understanding.

Analysis of the changes brought about by Law No. 14,874/2024

This new law represents a significant step toward maturity and evolution in the regulation of clinical research in Brazil, introducing provisions that are simultaneously more comprehensive and more specific than previous regulations. Its scope integrates and updates ethical, operational, and regulatory principles accumulated across various resolutions and guidelines, not limited to replacing or amending a single provision, such as CNS Resolution No. 466/2012.

In this sense, the analysis presented here does not aim to conduct a direct or schematic comparison between isolated regulatory instruments, but rather to situate the new law within a broader context of regulatory development, in which evolution is best understood through the sum of historical transformations and the consolidation of ethical standards and international best practices.

Centralization of Ethical Approval in Multicenter Studies

The provision for centralizing ethical review in multicenter studies, set forth in Art. 14, § 7, of Law No. 14,874/2024, constitutes one of the most innovative provisions of the new regulatory framework. This measure seeks to streamline the submission process, reduce duplication of reviews, and expedite protocol approval, especially in large-scale research. However, its implementation raises significant concerns regarding the preservation of ethical sensitivity to the sociocultural and educational specificities of local contexts.

The use of a single standard form for the analysis of all participating centers raises practical and regulatory concerns, particularly regarding the adaptation of the ICF to regional realities. Standardizing the ICF may be logistically efficient, but it compromises the document's comprehensibility when applied to populations with varying levels of literacy, local languages, or cultural particularities. In settings with a high prevalence of illiteracy, functional illiteracy, or communication barriers, the risk of obtaining formal but not truly informed consent becomes ethically unacceptable.

The legislation recognizes, in Article 24, Paragraph 1, the need to adapt communication to the participant's comprehension capacity, and, in Article 18, Paragraph 1, requires accessible language, especially for vulnerable groups. However, it does not provide operational guidelines to ensure that, in multicenter studies, these requirements are met in different locations. For example, there is a lack of clear criteria regarding the possibility and method of submitting adapted versions of the ICF by participating center, as well as regarding responsibility for these adaptations.

The absence of detailed regulations creates a series of uncertainties: is it the coordinating center's responsibility to ensure the ICF is adapted to local contexts, or will this task fall to each participating center? Will the ethical review of these versions be centralized by a single REC, even if it is unfamiliar with regional specifics, or will local RECs play a complementary role to ensure appropriate contextualization? These regulatory gaps may compromise not only the legitimacy of consent but also the public's trust in the ethical conduct of the research.

In summary, although the centralization of ethical review represents a potential gain in efficiency, it will only be ethically valid if accompanied by normative and operational safeguards that ensure the contextual adaptation of the ICF and the effective protection of participants' autonomy across all involved centers.

Signature by the principal investigator only

The legal requirement that only the principal investigator sign the ICF, as provided for in Art. 18, § 1 of Law No. 14,874/2024, raises important questions from an ethical-operational standpoint. Although the measure aims to reinforce accountability for the consent process, its literal application contradicts the very purpose of the law, which is to optimize regulatory procedures and increase efficiency in the conduct of clinical studies.

In multicenter studies or at sites with a large volume of participants, restricting the signing of the ICF to the principal investigator becomes logistically impractical. This requirement can cause significant delays in participant enrollment, jeopardize adherence to recruitment timelines, and disproportionately burden the principal investigator—side effects that compromise both the efficiency and feasibility of the study. From an ethical

standpoint, this concentration of responsibilities may, paradoxically, undermine the quality of the consent process, as it limits the role of team members who are in direct contact with participants and who, in many cases, are actually the ones explaining the study.

Signing the informed consent form is not a mere formality, but a milestone of accountability and confirmation that the participant has been adequately informed about the objectives, risks, and implications of the research. However, there is no technical, ethical, or regulatory justification for requiring that the principal investigator be the sole signatory, provided that the other professionals involved are formally authorized, trained, and registered as members of the study team. On the contrary, responsible flexibility regarding the signature—provided it is accompanied by proper delegation and institutional registration—is compatible with the principles of autonomy, efficiency, and ethical quality.

The absence of complementary guidelines regulating this requirement restricts the adaptability of research centers, especially those with more complex organizational structures. For the legal provision to fulfill its objective of protecting participants without compromising the operational feasibility of the research, it would be necessary to establish clear criteria for delegating the signature to qualified team members, while ensuring traceability, training, and ethical oversight.

Proposals for Ethical Regulation of Law No. 14,874/2024

Signing the ICF

The premise that only the principal investigator may sign the ICF, although seemingly intended to centralize ultimate responsibility, creates significant challenges for conducting multicenter studies. In large-scale research, this requirement results in logistical bottlenecks, delays in recruitment, and increased costs, hindering the desired efficiency. Such rigidity runs counter to the purpose of Law No. 14,874/2024, which aims to simplify and optimize processes to make Brazil a more competitive environment for clinical research.

Revisiting the flexibility provided for in previous resolutions, such as Resolution No. 466/2012, which allowed the delegation of consent acquisition to qualified team members, presents itself as a safe and efficient alternative. This model offers a solid foundation for ensuring shared responsibility, allowing the ICF to be signed by qualified sub-investigators. In this way, the operationalization of studies can proceed more efficiently, without compromising ethical standards or the quality of consent.

Allowing qualified sub-investigators to sign the ICF not only promotes operational efficiency but also upholds ethical commitment to participants. These professionals are fully qualified to ensure that consent is informed, providing volunteers with an adequate understanding of the study's risks and benefits. Adopting a more flexible approach, such as delegating responsibilities and allowing for local review of the ICF, helps balance efficiency and ethical protection, aligning legislation with its true objective: optimizing research processes without compromising the safety of those involved.

Centralization of Ethical Approval

The centralization of ethical review in multicenter studies, provided for in Law No. 14,874/2024, represents an important regulatory advance toward reducing bureaucracy and harmonizing clinical research approval processes. However, its effective implementation raises a central question: how can the ICF be operationalized in an ethical, accessible, and locally adapted manner, without compromising the regulatory efficiency intended by the standard?

The use of a single standardized ICF for all participating centers raises doubts about its ability to reflect the cultural, socioeconomic, and educational specificities of the different populations involved. In a country marked by profound regional inequalities, assuming uniform understanding among participants from such diverse contexts is, at the very least, problematic. The effectiveness of the centralized model will depend on the existence of mechanisms that ensure the contextualization of the ICF without diluting the operational gains sought by the legislation.

In this scenario, a proposal emerges to individualize the ICF within a centralized submission process: specific versions of the document, tailored to the reality of each participating center, could be integrated into the unified dossier submitted to the coordinating REC. However, this alternative presents new regulatory and operational challenges: who will be responsible for adapting the ICF to each context? Will the coordinating center centralize the submission of all versions? Will the REC responsible for centralized review be capable—technically and logistically—of assessing the contextual appropriateness of multiple versions of the ICF? Or will a hybrid model be necessary, with complementary review by local Research Ethics Committees?

These questions are not merely procedural, but touch on the core of consent's legitimacy: the ability to ensure that each participant, regardless of their geographic origin or sociocultural background, fully and freely understands the terms of the research to which they will be subjected. The absence of clear guidelines on how to reconcile normative centralization with the empirical diversity of research settings can lead to ethical inconsistencies and asymmetries in protection.

Given this, there is a need for a collaborative effort among coordinating centers, local researchers, Ethics Committees, and regulatory bodies to develop balanced solutions. Hybrid models of ethical analysis—which combine process streamlining with contextual safeguards—should be considered in situations where absolute centralization could compromise the intelligibility and validity of consent. After all, the commitment to

regulatory efficiency cannot overshadow the primary responsibility of research ethics: to protect, in an equitable manner, the autonomy and dignity of all participants.

CONCLUSIONS

The enactment of Law No. 14,874/2024 represents a significant regulatory milestone for clinical research in Brazil, addressing the need to streamline processes, reduce timelines, and provide greater legal certainty to those involved. However, its practical application, particularly regarding the ICF, requires careful attention to ensure that regulatory simplification does not undermine the ethical substance of consent or reduce it to a mere documentary formality[14]. The centralization of ethical review, however efficient it may be in operational terms, cannot disregard the cultural, linguistic, and educational differences that characterize the diverse contexts in which clinical studies are conducted.

The central challenge of the new legislation lies in balancing the pursuit of regulatory agility with the maintenance of robust ethical safeguards, especially regarding the protection of vulnerable populations. The adoption of a nationally standardized ICF, without clear provisions for contextual adaptation, risks compromising the document's intelligibility and, thereby, the very validity of consent. Similarly, the requirement for the principal investigator's sole signature, while well-intentioned from an accountability standpoint, imposes operational barriers in multicenter and large-scale studies without yielding proportional benefits for participant protection.

These points reveal a persistent tension between the principles of regulatory efficiency and research ethics, and demonstrate that simplistic solutions, if poorly calibrated, can create new risks rather than resolve them. In this regard, measures such as the formal delegation of responsibilities in the consent process and the inclusion of adapted versions of the ICF, evaluated under hybrid models of ethical review, emerge as viable alternatives to mitigate these dilemmas. Such mechanisms allow for the preservation of both the ethical integrity and the operational feasibility of studies, favoring a more balanced approach that is sensitive to the specificities of the Brazilian context.

The effective implementation of Law No. 14,874/2024 will therefore depend on clear, technical, and flexible complementary regulations capable of detailing operational procedures without compromising the fundamental principles of bioethics. As already indicated by health authorities, the subsequent regulatory process, to be conducted by the Executive Branch, should include transitional rules and guidelines that take into account the scale and complexity of the national clinical research system, which encompasses approximately 1.2 million users, 35,000 institutions, and more than 900 Ethics Committees, as well as thousands of institutions and millions of potential participants.

Finally, it is essential that this regulatory process remain open to critical input from the various stakeholders involved: researchers, ethics committees, institutions, healthcare system users, and legislators, in order to ensure that the practice of clinical research in Brazil continues to advance with rigor, responsibility, and social legitimacy. The consolidation of a modern and efficient regulatory environment must not be achieved at the expense of the ethical protection of participants, but rather in support of it. Only in this way will it be possible to transform the newly established legal framework into an instrument that simultaneously strengthens the international competitiveness of Brazilian science and the fundamental rights of those who participate in it.

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Authors' Contributions

Assis de Jesus Junior SC, Cerbino Neto J—Conception, planning (study design), data collection, analysis, interpretation, and drafting of the manuscript. Aguiar DF—Data collection, analysis, interpretation, and drafting of the manuscript. All authors approved the final version of the manuscript.

Conflict of Interest

The authors declare that there is no potential conflict of interest with peers, institutions, politicians, or financial entities related to this study.

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