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Ethical consent in research: from Nuremberg to artificial intelligence

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Abstract

Informed consent is a central ethical principle in research involving human subjects, evolving from the *Nuremberg Code*, established after the atrocities of World War II, to the contemporary challenges posed by artificial intelligence. Documents such as the *Declaration of Helsinki* and the *Universal Declaration on Bioethics and Human Rights* emphasize the importance of respecting participants' autonomy and rights. In Brazil, research ethics is regulated by the National Research Ethics System, with adapted norms, including the use of electronic consent, particularly after the COVID-19 pandemic. Artificial intelligence introduces ethical challenges such as transparency, explainability, and algorithmic biases, which can compromise participants' understanding of processes. The evolution of consent must keep pace with technological advancements, ensuring that individuals understand the risks and maintain control over their data, thus preserving their autonomy and dignity in a digital transformation era.

Keywords: Informed consent. Personal autonomy. Bioethics. Artificial intelligence.

Resumo

Consentimento ético em pesquisa: de Nuremberg à inteligência artificial

O consentimento informado é um princípio ético central em pesquisas com seres humanos, que evolui desde o *Código de Nuremberg*, estabelecido após as atrocidades da Segunda Guerra Mundial, até os desafios contemporâneos impostos pela inteligência artificial. Documentos como a *Declaração de Helsinque* e a *Declaração Universal sobre Bioética e Direitos Humanos* reforçam a importância de respeitar a autonomia e os direitos dos participantes. No Brasil, a ética em pesquisa é regulamentada pelo Sistema Nacional de Ética em Pesquisa, com normas adaptadas, incluindo o uso de consentimento eletrônico, especialmente após a pandemia de covid-19. A inteligência artificial introduz desafios éticos, como transparência, explicabilidade e vieses algorítmicos, comprometendo a compreensão dos participantes sobre processos. A evolução do consentimento deve acompanhar os avanços tecnológicos, garantindo que indivíduos compreendam os riscos e tenham controle sobre seus dados, preservando sua autonomia e dignidade em um cenário de transformação digital.

Palavras-chave: Consentimento informado. Autonomia pessoal. Bioética. Inteligência artificial.

Resumen

Consentimiento ético en investigación: de Nuremberg a la inteligencia artificial

El consentimiento informado es un principio ético central en la encuesta con seres humanos, que ha evolucionado desde el *Código de Núremberg*, establecido después de las atrocidades de la Segunda Guerra Mundial, hasta los desafíos contemporáneos impuestos por la inteligencia artificial. Documentos como la *Declaración de Helsinki* y la *Declaración Universal sobre Bioética y Derechos Humanos* destacan la importancia de respetar la autonomía y los derechos de los participantes. En Brasil, la ética en la encuesta está regulada por el Sistema Nacional de Ética en Encuesta, con normas adaptadas, incluido el uso del consentimiento electrónico, especialmente después de la pandemia de COVID-19. La inteligencia artificial introduce desafíos éticos como la transparencia, la explicabilidad y los sesgos algorítmicos, lo que puede comprometer la comprensión de los participantes sobre los procesos. La evolución del consentimiento debe seguir los avances tecnológicos, garantizando que los individuos comprendan los riesgos y tengan control sobre sus datos, preservando así su autonomía y dignidad en un escenario de transformación digital.

Palabras clave: Consentimiento informado. Autonomía personal. Bioética. Inteligencia artificial.

Research

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In a short story published in the post-pandemic period, the Mozambican writer Mia Couto addresses a wide range of long-standing and contemporary afflictions that plague humanity. The narrator, a miner, confesses: "Do not be mistaken, Father: you too work underground. In fact, in this world there is no work that is not that of a miner, whether carried out above or below the ground" [1]. With the authority of someone who knows the trade, he adds: "We tear out pieces from the world and, in that dark emptiness, gradually stop seeing one another" [1]. For the writer—who is also a biologist—*Homo sapiens* is one of the few species, if not the only one, capable of trivializing encounters, regarding the differences that so strongly characterize it with a kind of "attentive indifference" [2].

In this sense, informed consent is a particularly powerful instrument, especially in the field of human research ethics, as it necessarily breaks with the "attentive indifference" highlighted by Mia Couto. The miner character tells the priest that he has sinned by lying to a "scientist" who, in his words, seemed to have no patience to listen to him. The principle of consent, set forth in documents such as the *Universal Declaration on Bioethics and Human Rights* (UDBHR) [3], ensures the existence of an encounter between researcher and research participant and, thus, the visibility of, and attention to, the other. Establishing the indispensability of participants' autonomous consent, with freedom of choice and without coercion, is, in a way, to reaffirm the need to "see one another," including within research settings [4].

The term "consent" derives from the Latin *consentire*, composed of *con-* ("together") and *sentire* ("to feel" or "to perceive"), and thus reveals important underlying prerequisites. Being together is not enough; to become aware, one must first perceive—that is, know through the senses. In research ethics, being informed about something is therefore not synonymous with understanding it. Beyond a signed piece of paper or an informal conversation, consent, when properly obtained, is one of the most important practices in research involving human participants. It is not merely the formalization of a volunteer's permission to participate in research, but rather an explicit manifestation of respect for the autonomy and rights of the participant [5]. According to Manson and O'Neill [6], informed consent is obtained through different and complex types of communicative transactions and should not be seen as a mere "transfer of information" between electronic devices or between people.

During his confession to the priest, Mia Couto's character states that "we know we are together when a disaster causes the roof of the mine we all share, in this dark world, to collapse" [1]. Consent was introduced into research involving human participants precisely in the aftermath of one of the disasters mentioned by the miner. With the end of World War II, the 1947 *Nuremberg Code* [7] is regarded as the document that inaugurated the idea of informed consent. Other regulations were produced over the years, in contexts and with foundations that were at times divergent, yet convergent in their aim of protecting research participants. Noteworthy among these are the *Declaration of Helsinki*—predominantly hegemonic—and the UDBHR—with strong influence from intervention bioethics [5,8,9].

In Brazil, human research ethics is regulated by the National Research Ethics Commission (Conep) and the Research Ethics Committees (CEP), which together constitute the National Research Ethics System, formerly known as the CEP/Conep System. Conep's responsibilities include the drafting and updating of guidelines and regulations that underpin the protection of research participants. Legislation on research ethics, by definition, is not immutable; on the contrary, it has been continually challenged by countless technological advances. Consent and assent are now increasingly electronic, with researchers and participants separated spatially or temporally.

The issue that therefore arises is how to avoid "attentive indifference" in research conducted in virtual environments, ensuring that participants are given the opportunity to be heard. In this regard, Conep published two documents: Circular Letter 1, dated March 3, 2021 [10], and Circular Memorandum 23, dated October 17, 2022 [11], which respectively provide guidance on research procedures involving any stage conducted in a virtual environment and regulate the use

of electronic consent and assent for research participants and biobank donors.

The Fourth Industrial Revolution, marked by disruptive transformations in society resulting from technological evolution [12] has also imposed challenges on the process of obtaining consent, particularly with regard to artificial intelligence (AI). The aforementioned Conep documents align with various technological advances. Although they do not directly address the use of AI in research involving human participants, it is widely recognized that pressing ethical challenges must be considered. The massive use of algorithms—central to data extractivism—has reshaped ethical concerns, including within research ethics. One such concern is opacity, which manifests in the inability to objectively and transparently understand the processes through which input data are transformed into final outputs, concealing the steps and mechanisms underlying this transformation [13]. In the case of consent in AI-related research, this issue must be addressed, given that the act of consenting must necessarily be preceded by full clarification of the procedures to be carried out [14].

The complexity of AI algorithms and the use of large datasets may hinder participants' understanding of research objectives, methods, potential risks and benefits, and how their data will be collected, stored and used [15]. Algorithms that process such data, such as those based on machine learning, often operate in a non-transparent manner, making it difficult for participants to understand how their data are used and what the implications of such appropriation may be. The sheer volume and variety of data generate uncertainties regarding how personal data will be combined and analyzed, and the potential risks to privacy. Without clear and accessible explanations, the very idea of consent is compromised.

In light of the above, the objective of this study was, based on a critical review of the literature on the evolution of the consent process, to discuss the ethical challenges introduced by technological advances in the protection of rights and the promotion of autonomy of research participants, from Nuremberg to the emergence of AI technologies.

Method

A critical review of the literature was conducted to identify studies and documents addressing the challenges involved in obtaining consent in research, from its origins to the spread of AI technologies. The search was guided by the following research question: *What ethical challenges have been introduced by AI in the consent process in research involving human participants?*

The following inclusion criteria were established: (a) studies published in Portuguese, English and Spanish; (b) articles available in full text (open access); (c) restricted-access articles available through the CAPES Journals Portal (*Coordenação de Aperfeiçoamento de Pessoal de Nível Superior*); and (d) books, book chapters, theses, dissertations, legislation, official documents and resolutions. Articles published in non-indexed journals were excluded.

The following electronic bibliographic databases were searched: Embase (Elsevier), Medical Literature Analysis and Retrieval System Online/PubMed (MEDLINE), and the Virtual Health Library (VHL).

The following descriptors were used in both Portuguese and English: artificial intelligence, informed consent and personal autonomy.

In total, 75 articles were identified: 23 from the VHL, 34 from MEDLINE and 8 from Embase. In addition, a comprehensive search of the CAPES Journals Portal identified 10 articles that met the established criteria. After abstract screening, 32 articles were read in full, of which 27 were directly related to the research question.

In addition, 15 documents were analyzed—including laws, resolutions, official memoranda, circular letters, declarations and guidelines—as well as eight books, two interviews and one dissertation.

Results and discussion

Milestones in consent in research involving human participants

The requirement of consent in research involving human participants was established

Research

in the *Nuremberg Code*. Drafted in the 1940s, following Germany's surrender in World War II, in response to the atrocities committed against civilians and prisoners of war—in the name of science—by Nazi researchers [16], it is regarded as the "first code of ethics for scientific research" [17]. The document consists of ten principles addressing researchers' responsibilities and the rights of participants in scientific research, including the right to free choice [16]. Notably, the absolute necessity of voluntary consent is the first of the Code's ten ethical principles [18].

Although it represented a significant advance, this document was unable to bring about substantive changes in researchers' practices. The mistaken belief that the Code applied only to Nazi researchers contributed to the continued exposure of vulnerable groups to experimentation [19]. The fact is that, more than half a century after its publication, the *Nuremberg Code* is recognized more for its historical value than for its effective contribution to assessing the ethical soundness of research protocols, since, unlike other ethical codes, it has not been updated [16].

In 1964, still in Europe—more specifically in the city of Helsinki, Finland—the World Medical Association (WMA), at its 18th World Medical Assembly, adopted the *Declaration of Helsinki*. Its ethical recommendations are primarily directed at physicians, although they may be adopted by all those involved in research with humans participants [19]. The Declaration was also drafted in response to the criminal experiments carried out during the period of German National Socialism, emphatically establishing that the well-being of human beings "must take precedence over the interests of science and society" [20].

The *Declaration of Helsinki* thus has its roots in the *Nuremberg Code* but advances in certain respects. From its first version, it established the need for consent, while innovating by redefining what had been considered "absolutely essential" in the Code. It established, for the first time, the possibility of obtaining consent from legal representatives in cases of incapacity [21]. The *Declaration* also affirmed the importance of independent ethical review and the protection of vulnerable groups, highlighting the indispensability of obtaining written informed consent [8].

According to Ghooi [16], ethics is in constant evolution, which requires the regular review of ethical codes. While one of the main criticisms of the *Nuremberg Code* lies precisely in its static nature, the *Declaration of Helsinki* has undergone continuous transformation over the years. Following its initial publication, the Declaration has been revised nine times. Its most recent version was approved on its sixtieth anniversary, in October 2024, at the 75th General Assembly of the WMA, held symbolically in Helsinki [22].

Bibbins-Domingo and collaborators [23] argue that the *Declaration of Helsinki* is an ethical rather than a legal document, with a core that is, by definition, enduring. Guidance on emerging ethical issues has been progressively added to this core. In this sense, in the updated version, the term "subject" has been replaced by "participant," representing a significant advance: this is not a mere cosmetic revision of the text, but a deliberate rejection of the idea of passivity on the part of the individual agreeing to take part in research. In addition, electronic consent is explicitly addressed, and the guarantee of compliance with ethical principles during public health emergencies is affirmed—a paragraph clearly grounded in the recent experience of the COVID-19 pandemic.

Neither the *Nuremberg Code* nor the early versions of the *Declaration of Helsinki* addressed the participation of socially vulnerable groups in research [18]. The term "vulnerable" was incorporated into the body of the *Declaration* only in the 2000 review, a change with strong symbolic significance, as it marked the final year of the century in which the world witnessed profound dehumanization in research involving human participants. In research ethics, 2022 was remembered as the fiftieth anniversary of the discovery of the Tuskegee study [24], which began before the *Nuremberg Code*, in 1932, but ended after the *Declaration of Helsinki*, in 1972. The revelation that hundreds of African Americans had been left untreated for syphilis by an official public health agency of the United States highlighted the limited reach of existing regulations, as well as the absolute necessity of ensuring protection for individuals or groups in situations of vulnerability.

It was in this context, shifting from the European setting, that the *Belmont Report* was published in

the United States in 1979 [18]. The *Report* resulted from more than four years of work by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established by the US Congress in mid-1974 [18]. The creation of such a commission was considered innovative. The *Report* was grounded in the principles of respect for persons, beneficence and justice, and their specific applications—informed consent, assessment of risks and benefits, and the selection of research participants. According to Adashi and collaborators [25] the *Belmont Report* redefined human research ethics, serving as the "conceptual progenitor" of other documents not only of the United States but also internationally. The authors add that the *Report* was never intended to be timeless and, as such, is insufficient for addressing emerging ethical issues [25,26].

As noted, the *Belmont Report* highlighted informed consent as one of the key applications of its three principles, particularly respect for people. While the requirement to obtain consent was affirmed, there was considerable disagreement regarding research involving, for example, children and individuals with mental disorders or mental illness. The *Belmont Report* was only one of the texts produced by the Commission during its mandate [25]. Another report, entitled *Research Involving Children*, sparked the greatest divergence among Commission members, leading to internal dissent: the view of the child as an individual with autonomous interests and rights did not prevail in many moments of the debate, although the *Belmont Report* advanced certain aspects related to the autonomy of these participants [27].

Another foundational document in human research ethics is the set of guidelines published since 1982 by the Council for International Organizations of Medical Sciences (CIOMS): the *International Ethical Guidelines for Health-Related Research Involving Humans* [28], most recently updated in 2016. This document sets out 25 guidelines, three of which are directly related to consent. The concept of vulnerability, closely linked to that of free and informed consent, has been progressively incorporated into the CIOMS guidelines, moving "beyond a mere labeling approach." It has been argued, however, that the guidelines should be more prescriptive in providing researchers with concrete guidance on how to address the various forms of vulnerability [29].

With the consolidation of Latin American bioethics and its significant engagement with social, environmental and public health issues, it became necessary to establish new frameworks suited to local realities [30]. In this context, in 2005, the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the *Universal Declaration on Bioethics and Human Rights* (UDBHR). The *Declaration* comprises 28 articles, with the sixth and seventh specifically addressing consent. It also emphasizes respect for the privacy and confidentiality of research participants' personal information, constituting one of its most valued principles, particularly in light of the advancement and dissemination of AI technologies.

Digital revolution and informed consent

Technological advances have revolutionized the healthcare sector, providing new tools for diagnosis, treatment and care management. The benefits are not limited to clinical practice; AI tools can also be applied to health surveillance and health promotion, as well as to genomic research and the development of new drugs. However, the use of AI in healthcare and health research poses significant ethical challenges, particularly with regard to informed consent. As AI models become increasingly autonomous and complex, transparency about the role of these technologies in decision-making processes is essential to preserve individuals' autonomy and rights. International organizations, such as the World Health Organization (WHO), have emphasized the importance of establishing guidelines and governance frameworks to ensure that AI is developed and used in an ethical and responsible manner [31].

Regulations on research ethics are invariably time-bound, as they address a subject—ethics—that is intrinsically dynamic. Likewise, informed consent, the "cornerstone" of research ethics, has demonstrated adaptability to new contexts [32]. The advent of AI introduces a range of ethical issues related to autonomy, privacy, responsibility, transparency, exclusion, discrimination and stigmatization.

Informed consent must keep pace with these advances, ensuring that individuals understand the functioning, risks and benefits of AI and are able to make truly informed decisions. The lack of standardized, clear guidelines for consent in the context of AI may undermine trust between researchers and research participants, highlighting the need for robust ethical frameworks that integrate digital innovation with the protection of human rights. This requires adaptations to the informed consent process, ensuring that participants are genuinely aware of and agree to all the nuances involved in the research [33].

Consent presupposes information and clarification, and it is at this point that one of the ethical challenges associated with AI in human research becomes most apparent. AI technologies must be intelligible—i.e., understandable—not only to those who develop them but also to regulatory bodies and users, including researchers and research participants [31]. This requires the adoption of two strategies: increasing transparency regarding these technologies and making them explainable [31]. In this sense, explainability has gained considerable prominence in discussions on AI, aiming to ensure that decisions made by AI systems can be understood and justified, thereby mitigating ethical risks associated with the opacity of these systems [34].

Although AI has the potential to enhance participants' autonomy by enabling more informed and personalized decisions, the complexity inherent in automated systems plays a particularly central role in research ethics. The opacity of algorithms and the difficulty of rendering them explainable pose additional challenges to the consent process, as ensuring that participants fully understand the risks and implications of their participation becomes even more critical. The challenge, therefore, lies not in providing information but in ensuring that it is accessible and understandable, so that the complexities inherent in digital advances do not compromise individuals' capacity to exercise control over their own decisions [15].

Commenting on the *Declaration of Helsinki*, Shaw [35] argues that future revisions of the document should take into account the use of AI, including issues related to data governance. According to the author [25], rules governing who may access health data and under what circumstances vary significantly across countries and are strongly influenced by social, cultural and political contexts. Collective dialogue efforts, such as the *Declaration of Taipei*, have, in his view, been insufficient to adequately address this challenge [36].

The collection and use of large amounts of data to train AI algorithms raise questions about privacy, consent and responsible use. Issues such as algorithmic bias, transparency and accountability have also become key concerns [37]. Current methods of data collection and use compromise individuals' ability to provide fully informed consent. Among the main challenges are the lack of transparency in data collection and processing practices and the reuse of data for new purposes without the explicit consent of data subjects [15].

In addition to the WHO, organizations such as UNESCO and the European Union have proposed guidelines and ethical principles for the development and use of AI, aiming to ensure that the technology is used fairly, responsibly and for the benefit of society. These guidelines include principles such as transparency, safety and robustness, and human oversight, emphasizing the need to obtain informed consent for the use of personal data and to ensure that AI systems respect human rights [38].

AI research often involves complex algorithms and data collection processes that are not easily understood by civil society. The opaque nature of many AI systems can hinder transparent communication about risks and benefits, thus challenging the attainment of truly informed consent [39]. The extensive use of data, sometimes confidential and sensitive, raises significant concerns regarding privacy. Consequently, participants must be informed about how their data will be used, stored and protected. Anonymization is a commonly adopted strategy, although it is not entirely secure, especially when combined with other sources of information [14].

The evolution of informed consent reflects an ongoing commitment to protecting research participants; however, this process must advance alongside the rapid and tangible developments of emerging technologies. AI, in particular, requires a new level of transparency and clarity in informed consent to ensure that participants' rights are always respected and protected [40].

Informed consent remains a core ethical principle in research involving human participants. As AI use expands, consent standards must evolve to address the unique challenges posed by these technologies. Ensuring that participants are fully informed and that their rights and dignity are upheld is an ongoing responsibility of researchers. Research ethics must progress in step with technological advances, always guaranteeing transparency, protection and respect for individuals [41].

Beyond being merely a formal document, informed consent is a practice that legitimizes voluntary participation and safeguards participants' autonomy. With the growing use of AI across different research fields, ethical guidelines and procedures must be reviewed and expanded to address technological complexities. A lack of understanding of how algorithms operate, as well as the potential manipulation of personal data, can compromise the integrity of consent. Accordingly, researchers and ethics committees should develop new approaches that integrate these concerns and ensure the protection of participants' rights in an ever-evolving technological landscape [40].

To date, no formal document has been issued by national ethical bodies specifically addressing the use of AI in research involving human participants. However, the growing complexity of AI technologies underscores the urgency of engaging in in-depth discussions on ethical issues related to privacy, confidentiality, explainability and algorithmic bias. The process of informed consent, traditionally designed to ensure that research participants understand the associated risks and benefits, faces new challenges in the context of AI [42]. The opaque nature of many algorithms makes it difficult to clearly explain how decisions are made and how participants' data are processed. In addition, the presence of implicit biases in AI systems may result in inequalities in data treatment and in the conclusions drawn, thereby jeopardizing equity and justice in research.

Ethical reflection on informed consent in the age of AI highlights the need for continuous and dynamic dialogue between technology and ethics. Incorporating ethical principles from the earliest stages of AI system development is key to ensuring that scientific advances do not compromise fundamental rights and human dignity. Governance of these processes should be constructed collaboratively, involving ethics committees, researchers, technologists and civil society, so that consent practices keep pace with technological innovations and effectively protect participants' autonomy [15]. The future of informed consent in the age of AI will depend on the establishment of clear regulations and a collective ethical commitment that recognizes and mitigates the potential risks associated with the use of these technologies in scientific research.

Consent in Brazil

The first document on human research ethics in Brazil was Resolution 1 of the National Health Council (CNS) [43], which refers to a post-information consent form, semantically reinforcing the idea that the signing of the document should be preceded by information provided by the researcher [44]. It also addresses the notions of minimal risk and risk-free research, even raising the possibility of waiving consent. Despite having been published in 1988—more than forty years after the *Nuremberg Code* and close to the third revision of the *Declaration of Helsinki*—the text contains no reference to international research ethics or human rights regulations.

Less than a decade later, on October 10, 1996, the CNS approved Resolution 196 [45], which is undoubtedly a landmark in the regulation of research ethics in Brazil. The National Commission for Research Ethics was created, establishing the CEP/Conep System. The document comprises ten sections, one of which is entirely devoted to "free and informed consent," a term adopted to replace "post-information consent." In addition, the concept of vulnerability and its implications for obtaining consent were addressed for the first time [45].

On December 12, 2012, the CNS approved Resolution 466 [46], which incorporates the *Universal Declaration on Bioethics and Human Rights* (UDBHR) into its preamble and ceases to refer to the *Declaration of Helsinki*, whose sixth revision had been rejected in the *Córdoba Charter* [47]. This reflects efforts to broaden the scope of bioethics beyond biomedical and biotechnological

issues, as well as the development of bioethical thought in countries of peripheral capitalism. A section entitled "On the Process of Free and Informed Consent" was included, clearly emphasizing the ongoing nature of consent.

The resolution also introduced the concept of free and informed assent and the requirement of an assent form. Despite dating from the second decade of the twenty-first century, the document makes no mention of the use of technology in the consent process, and maintains the requirement of a written informed consent form [46]. Even after the enactment of Law 14,874/2024 [48], Resolution 466 [46] remains one of the main ethical references used by Brazilian researchers.

The COVID-19 pandemic posed new challenges to research ethics in Brazil, with a large number of new projects submitted to CEPs and Conep, often accompanied by urgency for approval due to the need to disseminate research findings. In this context, requests for consent waivers increased considerably. As a result of social distancing measures, researchers argued that it was not possible to obtain written informed consent from research participants. In response, in May 2020, Conep issued guidelines for the conduct of research and the operation of CEPs during the pandemic, proposing alternatives for obtaining consent [49], such as digital consent, initially on a provisional basis to address the needs of that particular moment.

Amid the uncertainties of the pandemic, Law 13,709/2018 (General Data Protection Law – LGPD) [50] came into force on September 18, 2020. There is common ground between the LGPD and research ethics involving human participants, particularly with regard to the protection of their rights. By establishing guidelines on privacy and the processing of personal data, the LGPD adds an essential layer of regulation to ensure that sensitive personal data are handled securely and responsibly. In the context of scientific research, especially in digital environments, where personal data are extensively used, the legislation functions as a mechanism to safeguard participants' dignity and privacy, minimizing risks and protecting confidentiality [51].

Although the LGPD and research ethics are aligned in terms of privacy and the protection of participants' rights, the practical application of both requires strict compliance on the part of researchers. This duality between the need for scientific advancement and the protection of participants' rights challenges researchers to maintain a critical and responsible stance, balancing legal requirements with a solid ethical approach [52].

The post-pandemic scenario accelerated the need to adapt the guiding documents on human research ethics in Brazil, and what was initially intended as provisional has become permanent. In March 2021, Circular 1 was published, providing "guidance on procedures for research at any stage in virtual environments," including multiple instructions related to consent [10]. The inclusion of electronic processes did not diminish the rigor of ethical review—on the contrary, it made it even more stringent, given that virtual environments introduce new risks related to breaches of confidentiality, data privacy and security.

However, the aforementioned circular [10] was not sufficient. In 2022, Official Circular 23 [11] was published, regulating the use of electronic consent and assent for research participants and biobank donors, and seeking to reconcile technological advances with the protection of participant autonomy [11]. The guidelines aim to minimize "attentive indifference" in research conducted in virtual settings.

The most recent Brazilian regulation on research ethics is Law 14,874, dated May 28, 2024, which originated from a bill supported by organizations such as the *Associação da Indústria Farmacêutica de Pesquisa* (Interfarma) and the *Aliança Pesquisa Clínica Brasil*. At the time, the goal was to establish a regulatory framework to facilitate the conduct of clinical research, especially in the development of new drugs and therapies, accelerating the authorization process and aligning Brazil with international standards [53]. The bill faced criticism from some sectors concerned about the protection of research participants, particularly regarding informed consent and ethical oversight.

Although Law 14,874/2024 [48] represents an important regulatory milestone for human research ethics, it presents weaknesses in term of participant protection. Several provisions of the law were vetoed, with only two vetoes maintained in the final enacted version. Moreover, issues

related to data protection and confidentiality, though mentioned in the law, were not extensively detailed, potentially leaving gaps for the misuse of participants' sensitive data [54].

Despite being the only Brazilian research ethics legislation enacted in the context of the widespread adoption of AI, the law does not address the use of emerging technologies in research involving human participants, nor does it specifically mention AI. However, it reinforces the importance of informed consent in the context of personal data protection, aligning with the principles of the LGPD and ensuring greater transparency and control for data subjects over their personal information [50].

This law [48] established the National System of Ethics in Human Research (SINEPSH), centralizing the oversight and regulation of research in order to ensure greater control and uniformity in the ethical review processes conducted by CEPs. The law also sets deadlines for research approvals, reinforcing the need for a fast and efficient review without compromising participant safety and rights. CEPs now have 30 business days to issue opinions on research proposals, and the National Health Surveillance Agency (ANVISA) has 90 days to review clinical trial applications [48].

Regarding informed consent, the new legislation weakens historical safeguards previously established by the CNS, such as strict requirements concerning access to information and clarity regarding risks and benefits, by relaxing procedures and allowing interpretations that may compromise participant autonomy. The replacement of the CEP/Conep system with a national research ethics body centralizes evaluations, limiting social oversight and reducing the plurality and independence of ethical reviews. It also reduces reporting requirements, negatively impacting transparency and responsiveness to adverse events [55].

Conep, in turn, issued strong criticisms of the law, highlighting its regressive nature and the absence of safeguards to ensure equity and representativeness in research protocols. These changes were met with broad opposition, reflecting a clash between economic interests and the defense of ethical principles, and revealing a regression in participant protection and in the consolidation of a research system guided by justice and scientific integrity.

Final considerations

The evolution of informed consent reflects significant changes in ethical and legal perspectives regarding participation in human research. Initially, there was no requirement to formalize consent, and decisions were often delegated to healthcare professionals or authorities. However, as debates surrounding human rights and individual freedom intensified, the need to obtain consent prior to participation in research became evident, reducing so-called "attentive indifference."

Less than a century after the Nazi experiments, humanity now has ethical rules and regulations that require participants to be fully informed about the objectives, risks and benefits of research, enabling them to make voluntary and informed decisions. Informed consent has thus strengthened individual autonomy. Given that science is in constant evolution, a sustained commitment to the principle of consent is a prerequisite for conducting ethical and responsible research.

In the context of AI, the emphasis on ethics and data protection further reinforces the importance of responsible practices that respect individual rights. Although there is a vast body of literature on the principle of consent and informed consent, the connection between these concepts and AI remains incipient. As AI becomes increasingly integrated into research, and as ethical dimensions such as algorithmic bias, explainability and transparency grow in importance, the urgency of regulating and thoroughly investigating this intersection becomes clear.

Without ethical regulations that specifically address AI in ICT processes, there is a growing risk that research participants' autonomy may not be fully protected. A regulatory framework must be designed to ensure that individuals understand the role of AI in the decision-making processes that affect them, guaranteeing meaningful control over their data and participation. Consent must be dynamic, ongoing and responsive to the complexities introduced by AI, including the possibility of revising or withdrawing consent as technology applications evolve.

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