Ethical Reflections by the Brazilian Society of Bioethics on Research Ethics

Diego Carlos Zanella

Elda Bussinguer

I would like to inform you that my presentation today does not have any conflicts of interest. My speech has been coordinated with Elda Bussinguer, the President of the Brazilian Society of Bioethics. The views and positions I will express here represent those of the Brazilian Society of Bioethics and do not generate any conflict of interest in relation to my own positions. I would also like to apologize for my limited speaking skills, which are not as strong as I would like them to be. Additionally, my voice is not very good today due to a sore throat.

The Brazilian Society of Bioethics was founded in 1995 with a mission to promote ethical standards in research and healthcare. From its inception, the Society has been deeply involved in addressing ethical issues in research, advocating for the responsible conduct of scientific studies, and ensuring the protection of human participants.

Although bioethics emerged late in Brazil, dating from the late 1980s and early 1990s,[1] during this period, bioethics was already present in Brazil and some people were already working with bioethics, but there was not yet a convergence of these individuals.[2] So the creation of a national entity was a significant milestone for the convergence of people with interests in bioethics and for its dissemination.

> It seems to have been important for the implementation and development of bioethics in Brazil that, since the first administration, one of the main goals was to bring together all individuals from various fields of knowledge who were interested in bioethics.[3]

The Society has played a pivotal role in fostering dialogue and collaboration

---

[1] Cf. DINIZ, Debora; GUILHEM, Dirce Bellezi; GARRAFA, Volnei. Bioethics in Brazil. *Bioethics,* v. 13, n. 3-4, 1999, p. 246.

[2] Cf. HOSSNE, William Saad; ALBUQUERQUE, Maria Clara; GOLDIM, José Roberto. Nascimento e desenvolvimento da bioética no Brasil. *In:* ANJOS, Márcio Fabri dos; SIQUEIRA, José Eduardo de (orgs.). *Bioética no Brasil: tendências e perspectivas.* Aparecida, SP: Ideias & Letras, 2007, p. 148; cf. CREMESP. *Revista Ser Médico,* edição 71, abril de 2015. Seção Debate: Ética e Bioética. Entrevista com William Saad Hossne e Regina Ribeiro Parizi Carvalho.

[3] HOSSNE, William Saad; ALBUQUERQUE, Maria Clara; GOLDIM, José Roberto. Nascimento e desenvolvimento da bioética no Brasil. *In:* ANJOS, Márcio Fabri dos; SIQUEIRA, José Eduardo de (orgs.). *Bioética no Brasil: tendências e perspectivas.* Aparecida, SP: Ideias & Letras, 2007, p. 148.

among professionals from various fields, including medicine, philosophy, law, and social sciences. By organizing conferences, workshops, and educational activities, the Brazilian Society of Bioethics continues to contribute significantly to the advancement of bioethical standards in Brazil and beyond.

The Brazilian Society of Bioethics actively participated in the improvement of research ethics in Brazil, especially in the process of revising Resolution No. 1, dated June 13, 1988, of the National Health Council (CNS).[4] This revision process, which took place during the I Brazilian Congress of Bioethics from June 26 to 28, 1996, and in several other meetings with this purpose, culminated in the presentation of Resolution No. 196, dated October 10, 1996, of the National Health Council (CNS).[5] This resolution created the Brazilian research ethics system, namely, the Research Ethics Committees (CEP) and the National Research Ethics Commission (CONEP), known as the CEP/CONEP System.

The history of research ethics in Brazil is a narrative of progressive development influenced by both national and international contexts and which was initiated in 1988. The framework of ethical research in Brazil has evolved considerably over the past few decades, with significant milestones marking its growth.

In the mid-second half of the last century, Brazil, like many other countries, had limited formal structures for research ethics. Ethical considerations were often handled on an ad-hoc basis, relying on the discretion of individual researchers and institutions. However, as scientific research expanded, the need for more systematic oversight became evident.

The global awareness of ethical standards in research was significantly influenced by historical events such as the Nuremberg Trials and the subsequent Declaration of Helsinki, which emphasized the need for ethical principles in medical research involving human participants. These international milestones resonated within the Brazilian scientific community, prompting discussions and actions towards more formalized ethical guidelines.

A pivotal moment in Brazil's history of research ethics came in 1996 with the publication of Resolution No. 196/1996 by the National Health Council (CNS). This resolution laid the foundation for ethical standards in research involving human

[4] Cf. BRASIL. *Resolução CNS nº 1,* de 13 de junho de 1988.
[5] BRASIL. *Resolução CNS nº 196,* de 10 de outubro de 1996.

participants in Brazil. It outlined the need for informed consent, the protection of vulnerable populations, and the establishment of Institutional Review Boards (IRBs), known in Brazil as Research Ethics Committees (RECs).

Following Resolution No. 196/1996, Brazil continued to refine its ethical guidelines. The establishment of the National Commission for Research Ethics (CONEP) further strengthened the oversight of research ethics. National Commission for Research Ethics plays a crucial role in coordinating the activities of Research Ethics Committees across the country and ensuring compliance with national and international ethical standards.

In 2012, Resolution No. 466 replaced Resolution No. 196/1996, providing updated guidelines that reflect the evolving landscape of research ethics. This resolution takes into consideration other international documents on research ethics and human rights, such as Nuremberg Code, from 1947; the Universal Declaration of Human Rights, from 1948; the Declaration of Helsinki, adopted in 1964 and its versions from 1975, 1983, 1989, 1996 and 2000; the International Pact regarding Economic, Social and Cultural Rights, from 1966; the International Pact regarding Civil and Political Laws, from 1966; the Universal Declaration regarding Human Genome and Human Rights, from 1997; the International Declaration regarding Human Genes Data, from 2003; and the Universal Declaration regarding Bioethics and Human Rights, from 2005.

Brazil continues to evolve its research ethics landscape, responding to new challenges and advancements in science and technology. The country is committed to ensuring that ethical considerations keep pace with scientific progress, safeguarding the rights and well-being of research participants.

The history of research ethics in Brazil is marked by significant progress and a commitment to upholding the highest ethical standards. Through continuous refinement of guidelines and the establishment of robust oversight mechanisms, Brazil has developed a comprehensive framework that ensures the ethical conduct of research involving human participants.

It is true, not everything is rosy in the development of research ethics in Brazil. Recently, the National Congress approved a law on research ethics, namely, Law No. 14,874, dated May 28, 2024, which will come into effect in two days.

Since the inception of research ethics in Brazil in 1988, 36 years ago, much has

been done for the development of bioethics and research ethics in Brazil. And the instances of social control have played a prominent role. Social control presupposes the effective participation of society, not only in overseeing the application of public resources but also in the formulation and monitoring of policy implementation.[6]

However, there are attempts to interfere to minimize the role of social control.[7] This is the case with the new research ethics law approved in Brazil, namely, the Law No. 14,874, dated May 28, 2024, which provides for research involving human beings and establishes the National System of Ethics in Research with Human Beings.

The problem here is that Brazil already has a national system of research ethics, namely, the CEP/CONEP System, which the mentioned law does not even mention. The National Research Ethics Commission (CONEP) and the National Health Council (CNS) have responsibilities to ensure the protection of participants in clinical research. In this sense, the changes proposed by the mentioned law may remove autonomy from the National Research Ethics Commission (CONEP), weaken the security of research participants, and favor commercial interests without considering ethical aspects. In the national and international scenario of clinical research, as pointed out in the Clinical Research Action Plan in Brazil:

> Brazil has the potential to attract clinical research due to its large and diverse population; the existence of a public health system, which facilitates patient recruitment and follow-up; the high incidence of the most prevalent diseases in developed countries; the existence of ethical research standards compatible with other countries, qualified professionals, and a good infrastructure of hospitals and reference centers for phase III clinical trials.[8]

Thus, it can be observed that Brazil is an important destination for multicenter clinical research due to its mixed-race population with great genetic diversity. This characteristic is important for phase III studies, as the objective of this phase is to test the drug or vaccine on the largest number of people with different characteristics to analyze its efficacy and possible variables.

Phase III studies are often portrayed as the gold standard in clinical research, yet

---

[6] Cf. SALGUEIRO, Jennifer Braathen; FREITAS, Corina Bontempo Duca de. Regulamentação ética da pesquisa no Brasil: pepel do controle social. *Revista Bioética,* v. 30, n. 2, 2022, p. 239-240.

[7] Cf. FONSECA, Claudia. Situando os comitês de ética em pesquisa: o sistema CEP (Brasil) em perspectiva. *Horizontes antropológicos,* v. 21, n. 44, 2015.

[8] BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde. Departamento de Ciência e Tecnologia. *Plano de ação de pesquisa clínica no Brasil*. Brasília: Ministério da Saúde, 2020, p. 20.

a critical examination reveals that many of these trials function less as genuine scientific inquiries and more as a service to the global pharmaceutical industry. Rather than being driven by a quest for new knowledge or the desire to address significant public health needs, these studies frequently prioritize the commercial interests of pharmaceutical companies. This is evident in the design and conduct of many Phase III trials, which are often tailored to meet regulatory requirements and market demands rather than to answer essential scientific questions. The focus on large-scale, multi-center trials also reflects a tendency to produce data that supports market approval rather than advancing medical science. Consequently, the integrity of the research process is compromised, as these studies become tools for profit generation rather than true endeavors in scientific discovery. This blurring of the line between research and service provision undermines the credibility of the entire clinical trial process, calling into question the validity of the findings and their contribution to the broader scientific community.

Returning to the context of research in Brazil, the process of conducting a clinical study begins currently with the approval of the research protocol by the CEP/CONEP System. The system operates independently of the Federal Government to protect the rights of research participants, always guided by ethical values. The system is also an international reference due to the comprehensiveness and robustness of its regulations. It is worth noting that the CEP/CONEP System performs the ethical analysis of research protocols involving human participation. The National Health Surveillance Agency (ANVISA) is responsible for authorizing experimental drugs for use in research and operates with different timelines from the CEP/CONEP System.

It is undeniable that there is a need for greater investment in clinical research. However, this development should not occur to the detriment of research participants. As stipulated in the Clinical Research Action Plan in Brazil, all actions presented on ethical regulation have been executed by the National Research Ethics Commission (CONEP), with the aim of improving the system and everyone involved.[9] This demonstrates that the ethical regulation sector of clinical research in Brazil is constantly striving to improve itself to contribute to the development of clinical research in the country. Moreover, it is

[9] Cf. BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde. Departamento de Ciência e Tecnologia. *Plano de ação de pesquisa clínica no Brasil*. Brasília: Ministério da Saúde, 2020, p. 32.

also concerned with protecting and maintaining the guarantees for research participants that have been secured since the creation of the CEP/CONEP System in 1996.

Increasing the volume of clinical research in Brazil is unattainable among the growing weakening of research ethics guidelines. Robust and unwavering ethical standards are the cornerstone of credible and humane research practices. As such, any erosion of these standards undermines not only the integrity of the research but also the trust and safety of its participants.

It is imperative to thoroughly qualify researchers in the ethics of human being research. Without a deep understanding and commitment to ethical principles, researchers may inadvertently cause harm or fail to protect the rights and well-being of participants. Comprehensive ethics training ensures that researchers are equipped to navigate the complex moral landscape of clinical studies, balancing scientific advancement with the respect and dignity owed to each participant.

Moreover, clear communication about rights and guarantees is crucial for research participants in experimental trials. Participants must be fully informed of their rights, the nature of the study, potential risks, and the measures in place to protect them. This transparency fosters trust and empowers participants, allowing them to make informed decisions about their involvement.

Furthermore, the provision of post-trial access to treatments is a critical ethical consideration, particularly for chronic diseases. Recent legislative proposals to limit this obligation undermine the ethical responsibility of researchers and sponsors to continue providing effective treatments discovered during trials. Such changes threaten to reduce participant trust and could deter individuals from participating in future research, thereby stifling scientific progress.

Investing in the development of clinical research in Brazil also necessitates adequate infrastructure and funding. This includes ensuring that research facilities are well-equipped and that there is sufficient financial support for both the operational aspects of trials and the long-term follow-up of participants.

Finally, fostering a culture of ethical research requires continuous oversight and public engagement. Independent bodies such as the CEP/CONEP System must remain vigilant and autonomous, ensuring that all research complies with ethical standards. Public awareness campaigns can also play a role in educating potential participants about

their rights and the importance of ethical standards in research.

In conclusion, the potential for expanding clinical research in Brazil hinges on maintaining and strengthening ethical guidelines, providing comprehensive ethics education for researchers, ensuring transparent communication with participants, and investing in robust research infrastructure. Only through such measures can Brazil emerge as a leader in ethical clinical research, attracting global partnerships and contributing significantly to medical advancements.