saúde
EM DEBATE

Inaep: the ethics of an influential elite in opposition to the ethics shared with democratic social control

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BRAZIL HAS JOINED THE LIST OF COUNTRIES THAT REGULATE RESEARCH ethics with humans, starting in 1996[1]. Until that date, Brazilian researchers had to evaluate their projects through rare local ethics committees at a few academic institutions or pharmaceutical companies. Some references regarding the ethical nature of the research were provided by committees located abroad, notably in Europe or North America, which were known by the three-letter acronym 'IRB' (Internal Review Board).

Resolution No. 196, of October 10, 1996[1], from the National Health Council (CNS), established the National Research Ethics Committee (Conep)—whose members are elected by civil organizations that participate in the CNS. The resolutions of the Committee have always been discussed and approved by the CNS Plenary before being ratified and published by the Minister of Health. Since its creation, the composition of Conep ensures parity between users and volunteers involved in research, and during human research projects, a system is established to protect their rights.

In this way, long-developed resolutions regarding health research emerged, not only related to 'clinical research', which has a specific interest in testing diagnostic, treatment, and follow-up technologies for users of the Unified Health System (SUS)[2]. The broad spectrum of research of human interest also included social, anthropological, psychosocial, political, economic, and administrative studies, linking them to pharmacological test fields and technological procedures involving human subjects[2]. Over the 29 years of operation, normative, sub-legislative resolutions (ministerial ordinances) emerged to address the lack of laws or decrees regulating human research in Brazil.

During the politically turbulent year of 2015, when the coup d'état that ousted President Dilma Rousseff was being orchestrated in 2016, the Federal Senate approved Bill No. 200[3], initially authored by Senators Ana Amélia, Waldemir Moka, and Walter Pinheiro. This bill was processed in the Chamber of Deputies under No. 7,082, in 2017[4]. The 'urgent regime' processing ended on November 8, 2023, when it was transformed into Ordinary Law No. 14.8742 on May 29, 2024. On June 17, 2025, the Presidential vetoes were overturned, and these were published in the Official Gazette of the Union on July 2, 2025[5].

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The efforts of social organizations affiliated with academia and the SUS health services to mitigate the damage caused by the law, which filled a void in the country's health policy, proved futile. Numerous appeals were made to senators and deputies to consider that the rights of Research Participants' Representation (RPP) should be the primary goal of any law intended to regulate ethics in research involving humans. The Brazilian Center for Health Studies (Cebes), the Brazilian Association of Collective Health (Abrasco), and the Brazilian Society of Bioethics (SBB) made futile visits to the legislators' offices, pleading for attention to ethical aspects and the importance of defending RPP. The final law introduced aspects that would never have been included if plural academic societies had, at a minimum, been consulted. The 'Bad Law' was enacted, and the Presidency of the Republic vetoed specific provisions deemed minor and insignificant compared to the greater harms it caused. Some of these vetoes were eventually overturned in a session of the National Congress.

Why is it said that the law is bad? The main reason is that it requires the Committee that assesses research ethics to be overseen and selected by a representative of the Executive Branch—the Minister of Health—advised by an advisory group appointed by a National Secretary, who is subordinate to the Minister.

Law No. 14,874 included a cruel detail: volunteers in positive clinical trials lose the right to free access to the new medication or technology five years after the trial ends. This may be 'reevaluated' by the principal research coordinator or by representatives of the 'sponsor.' It is no longer obligatory to provide medication to those who volunteered, whether they were in the test or control group. If sponsors deny requests, the Unified Health System (SUS) must pay for the provision of the tested and approved new technology, despite the risks volunteers will face after the fifth year.

The new law destroyed the CNS's central representative role, whose focus on RPP disappeared along with almost 30 years of normative experience articulated by Conep. Similarly, the national coordination, centralized in Conep, of over 16,000 volunteer consultants in about 900 Research Ethics Committees (REC), which were created based on the CNS's experience with health research, not only with 'clinical research', also disappeared. To meet the wishes of pharmaceutical industries and health technology producers, with specific interests in recruiting 'volunteers', approving, and selling their products, the law considered health research involving humans to be only of a clinical and technological nature. The abandonment of RECs to their own local and international conflicts is cruel, as it creates an independent republic in each REC, with local control exercised by various forces and powers that may steer efforts for scientific equity within the country.

One negative aspect of this law was assigning to the Legislative Branch a role exclusive to the Executive Branch: creating government structures, allocating budgets, and determining ways to carry out operational activities. This mismatch between the Legislative and Executive branches is called a formal initiative flaw. The law, originating from parliament, created and organized a federal public administration body (National Research Ethics Board – Inaep in the Ministry of Health), which should have been solely initiated by the President of the Republic (art. 61, § 1, II, "b" and "e", of the Federal Constitution of 1988)[6]. This was the reason why SBB filed a Direct Action of Unconstitutionality before the Federal Supreme Court (STF) against Law No. 14,874/2024.

Another negative aspect of the law was the subordination of research ethics to an executive agency, with constant contact with the interests of producers and testers of new health technologies. Those who develop new technologies are interested in seeing them on the public or private market, which creates a conflict of interest with those seeking to incorporate new health technologies, whether 'hard' or 'soft,' that are compatible with the

ethical defense of research participants[7]. During the 2019-2022 period, the Brazilian government sought to approve the use of ineffective medications and to prevent the use of vaccines and social distancing to supposedly control the COVID-19 pandemic. Had they had the means provided by the new 'clinical research' law, they would have been able to do what they desired without facing scientific, social, and legal resistance.

With the publication of Law No. 14,874/2024, we entered a period of 'legislative void' starting in August 2024. The law did not specify whether to maintain the CNS's regulations in effect, nor what to do with Conep, which continued to operate and review an average of 300 new research projects per month, receiving sensitive, multicenter, international projects, and projects involving populations considered vulnerable, such as indigenous peoples, quilombolas, and other traditional communities. As the law did not foresee that the old structure would no longer function, there was a period during which previous regulatory ordinances could be legally contested, as well as the opinions that approved or disapproved new projects. Without a federal decree or a ministerial ordinance, nothing had legal validity; everything was considered non-existent from a legal and juridical standpoint.

There was a one-year period, from August 2024 to August 2025, during which renewed expectations and appeals were made by Cebes, Abrasco, SBB, and the Front for Life for the President and the Minister of Health to issue a federal decree that could mitigate the adverse effects of the law by implementing damage control measures, such as incorporating the structure and operations already tested and coordinated over nearly 30 years 'into' Inaep. Thus, the slogan 'Conep in Inaep' was created to request that a federal decree promote conflict-of-interest controls, subordination to the industrial capital sponsoring the research, and maintain ethical oversight of national research projects.

During the political-administrative phase of implementing the law approved in 2024, members of Conep attempted to revisit essential aspects, such as the existence of ethical and democratic social controls, so that the President of the Republic would sign the regulation decree of the law and the Minister of Health would issue the operational order for the future decree. It is noteworthy that this occurred in Brazil in parallel with what, in April 2025, the government of the United States of America did by dismissing the panel of experts responsible for ethics in research at the National Institutes of Health (NIH), an agency linked to the Department of Health and Human Services (DHHS).

After more than a year of negotiations, misunderstandings, political and administrative silences, written protests on websites, and the emergence of new lobbyist associations funded by industrial and technological powers, finally came Decree No. 12,651, of October 7, 2025, which worsened Law No. 14,874/2024[8]. The requests from scientific and academic associations were ignored because "*a Decree does not legislate on what the Law provides*". It was useless to argue that the decree can add provisions that the law does not include, which would allow for the 'regulation' of the 'Conep within the Inaep'. Thus, nothing was done.

A new ordinance issued by the National Secretary of the Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex (Sectics) reduces the role of the CNS to 6 representatives (18%) of the voting quota of a Committee of 33 participants, of whom 15 will be persons with notable expertise appointed by the Minister of Health[9]. Once such a committee is established, the Conep disappears from the map with its entire body linked and referenced to standards from 1996-2025, and the Ethics Committees become autonomous centers, regulated by Inaep within the new structure and composition.

That is why, given the failure of all requests, most of the Councilors of Conep decided to

resign and no longer issue opinions on new research projects. If they did, they would be exposing themselves legally, and all the work could be invalidated through administrative acts by the Minister or Sectics[10].

It will always be possible to find legal, administrative, and political solutions to the deadlocks in public health in Brazil. Since 1976, Cebes has taken positions on organizational issues, such as the More Doctors Project and, more recently, the Now Has Specialists Project, critically arguing for the need to address the legal, formal, and political aspects of these major structural initiatives of SUS. There is an expectation that, by fostering critical awareness, analytical contributions, and participatory engagement, it will be possible to properly promote what can be seen as a failed policy of trying to reconcile with opponents while ignoring allies. Let us look to the future.

Colaborator

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