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THE DECREE REGULATING THE LAW ON RESEARCH INVOLVING HUMAN BEINGS HAS BEEN PUBLISHED

On October 8th, 2025, Decree No. 12,651/2025 was published: the long-awaited regulation of Law No. 14,874/2024, which brought the discipline of research involving human beings under legal jurisdiction.

The Law had left some key points to be defined in regulations, which was still causing some uncertainty in the sector. Now, the Decree expressly provides that:

* The rules of the National Health Council (CNS) that do not contradict the Law and the Decree will remain valid until the publication of new regulatory rules by the National Research Ethics Authority;
* The National Research Ethics Commission (CONEP) will continue to act as an appeals body until the members of the National Research Ethics Authority take office;
* Until a new assessment is made by the National Research Ethics Authority, Research Ethics Committees (CEPs) already credentialed and accredited for ethical analysis in research with human beings are considered credentialed and accredited.

We also highlight other key aspects brought about by the Decree:

I. The National Research Ethics Authority will be coordinated by the technical area of science and technology of the Ministry of Health. The publication of a specific act regarding its functioning, deliberative procedures, members, etc. is awaited.

II. The body is installed with a minimum quorum composed of an absolute majority of the nominees, among them:

    * 6 representatives appointed by the Ministry of Health (mandatory: one Coordinator of the National Research Ethics Committee and one substitute Coordinator);
    * 6 representatives appointed by the CNS;
    * 2 representatives appointed by the Ministry of Science, Technology, and Innovation;
    * 1 representative appointed by the Ministry of Education;
    * 1 representative appointed by ANVISA;
    * 2 representatives appointed by the National Council of State Research Support Foundations; and
    * 15 expert representatives with renowned knowledge and relevant experience in the field of ethics in research involving human subjects, to be selected through a public selection process, with 3-year terms (reappointment permitted).

III. Definition of criteria for classifying the degree of risk in research involving human beings, subject to different procedures for the corresponding research protocols.

IV. Specific rules of the National Research Ethics Authority shall govern:

    * the credentialization and accreditation of RECs;
    * the preparation, presentation, and ethical analysis of the plan and program for providing post-study treatment;
    * the plan for monitoring and assisting participants in discontinued clinical trials;
    * the operation of biobanks and biorepositories.

V. Mention to a platform maintained by the Ministry of Health that integrates registration, protocol, information, and analysis of research involving human subjects – such as the Brazil Platform provided for by CNS Resolution No. 466/2012 – with a public database and periodic updates of research, ensuring the protection of confidential information and personal data (including sensitive data), with access restricted to authorized bodies, in alignment with the LGPD.

VI. Requires CEPs to ensure confidentiality and access control over protocol documents and data; and limits the use of biological material and data to the project purpose unless the Free and Informed Consent Form expressly authorizes future research, subject to the LGPD and rules to be issued by the National Research Ethics Authority.

VII. Where personal data — including sensitive data — are processed in the conduct of research, the provisions of the LGPD must be observed, including identification of a lawful basis, a specific purpose, security measures, and safeguards for sensitive data.

VIII. The Secretariat of Science, Technology, and Innovation and the Economic-Industrial Health Complex will establish a working group by 7 November 2025, to develop complementary and regulatory procedures related to the functioning of the National Research Ethics Authority and the implementation of the National System of Ethics in Research with Human Beings.

IX. Specifically with regard to clinical research, the possibility of an integrated ethical and health assessment procedure between the National Research Ethics Authority and ANVISA is envisaged.

X. Possibility for the National System of Ethics in Research with Human Beings to establish technical advisory groups to support the processes of accreditation, certification, and supervision of CEPs. Its members may be appointed to conduct audits, issue reports, propose recommendations, and assess the compliance of institutions with applicable standards.It is hoped that the practical application of Decree No. 12,651/2025, even during the transition period until the National Research Ethics Committee is fully operational, will make it possible to assess the adequacy of the current regulatory framework for research involving human beings.

At the same time, the Brazilian Society of Bioethics is questioning the constitutionality of Law No. 14,874/2024 before the Brazilian Supreme Court (STF). According to the entity, the rule would transfer the cost of treatments after the completion of clinical studies to the SUS, would not ensure society's participation in the governance of research ethics, would weaken the informed consent of research participants, etc.

The case is awaiting a report to be prepared by Minister Cristiano Zanin and may impact the new legislative and regulatory framework applicable to research involving human beings as a whole.

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