New rules

Research with Human Subjects

Lefosse

Main innovations

On May 28, 2024, was sanctioned the **Law No. 14.874/2024**, which addresses research with human subjects in Brazil and establishes the National System of Ethics in Research.

The text brought important news in this subject.

SEE BELOW

The National System of Ethics in Clinical Research with Human Subjects

Pending regulation by an act of the Executive Branch.

The National System of Ethics in Clinical Research with Human Subjects

It is segmented into two instances

National body for research ethics.

Issue regulations on research ethics.

Accredit, oversee and monitor **CEPs**.

CEPs

Analysis body for research ethics, represented by the **Research Ethics Committees (CEPs).**

CEPs

Research Ethics Committees

CEPs must act as ethical analysis bodies for research and

- Be composed of a multidisciplinary team
- Be accredited by the national body for research ethics
- Have adequate infrastructure to carry out their activities
- Have one representative of the research participants in their composition
- Among other requirements

Post-study supply

Prior to the start of a clinical study, the sponsor and the investigator must submit a **post-study access plan** to the CEP.

Post-study acess plan

CEPs

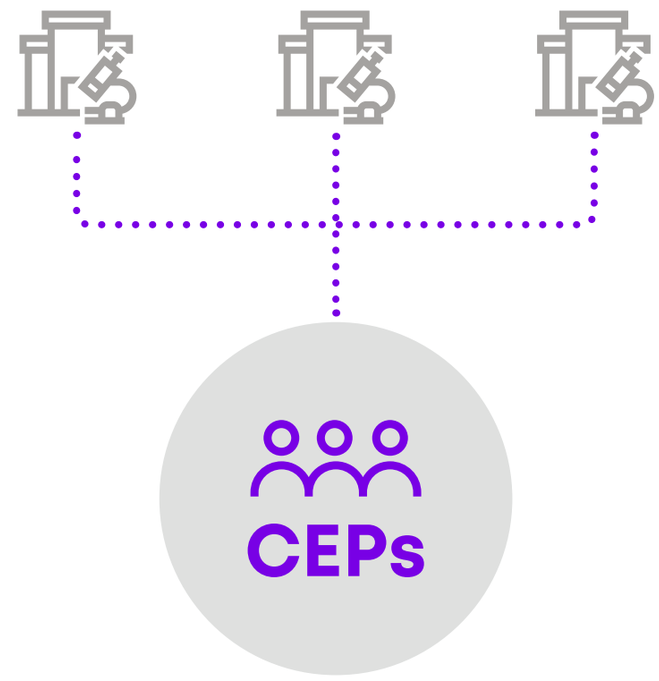
If a drug needs to be supplied after a clinical study:

A post-study supply program should be prepared.

Post-study supply may be interrupted in the following cases:

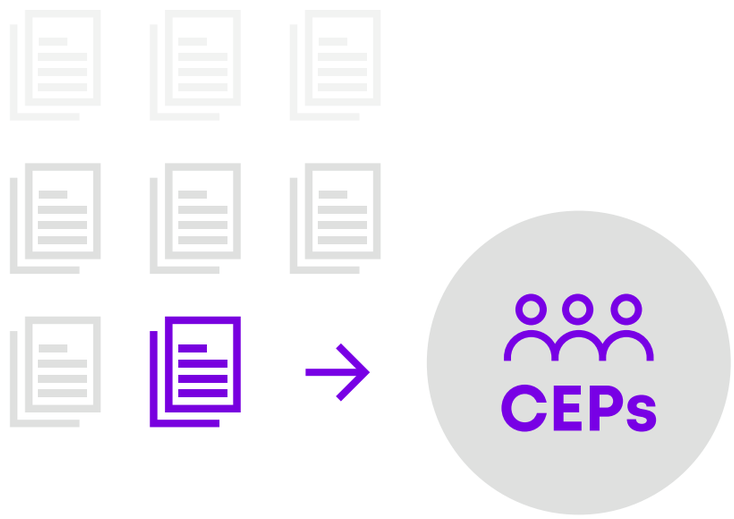
- The research participant's own decision
- Cure of the disease or health problem, or introduction of a satisfactory therapeutic alternative
- Lack of benefit from continued use of the experimental drug or occurrence of an adverse reaction that makes continued use of the drug impossible
- Impossibility of obtaining or manufacturing the investigational product for technical or safety reasons
- Availability of the experimental drug in the public healthcare system

Multicenter Studies



If the ethical analysis of the research involves more than one study center in the country, **it will be carried out by a single CEP,** preferably the one associated with the center coordinating the research.

Informed Consent Form

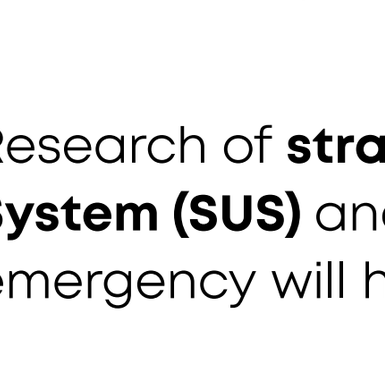


The ICF must be updated and submitted to the CEP that approved the research **whenever new relevant information comes** to light that could change the research participant's decision to participate.

Deadlines for Analysis

The CEP's ethical analysis of the research, with the issuance of an opinion, **cannot exceed 30 working days** from the date of acceptance of all the research documents.

Research of **strategic interest to the Brazilian Unified Health System (SUS)** and relevant to the management of a public health emergency will have priority in the ethical analysis.



ANVISA **has 90 working days** to analyze the primary applications for clinical studies with human subjects, for the purpose of registering the product under investigation.

In such cases, the opinion on the research shall be issued within a period not exceeding 15 days from the date of receipt of the research documents.

If ANVISA does not give its opinion within 90 days, *clinical development can begin, provided it received the relevant ethical approvals.*

General Rules

Ethical and scientific requirements must be observed in the development of the research, including:

- Respect for the rights, dignity, safety and well-being of research participants
- Conducted on the basis of a risk-benefit ratio that is favorable to the participant
- Conducted in accordance with a protocol approved by the CEP
- Ensure the competence and technical and academic qualifications of the professionals involved in the conduct of the research
- Respect the privacy of the research participant and the rules of confidentiality of their data, guaranteeing the preservation of the secrecy of their identity
- Provide medical assistance to participants

Participation in the research is voluntary.

Participants may not receive remuneration or benefits of any kind for their participation, except in the case of Phase I clinical trials or bioequivalence studies, provided that the legal requirements are met.

Participants may leave the research at any time,

free of charge and without prejudice, and may be compensated by the research sponsors for any harm suffered as a result of their participation, with the right to receive the medical assistance necessary to mitigate the harm suffered.

General Rules

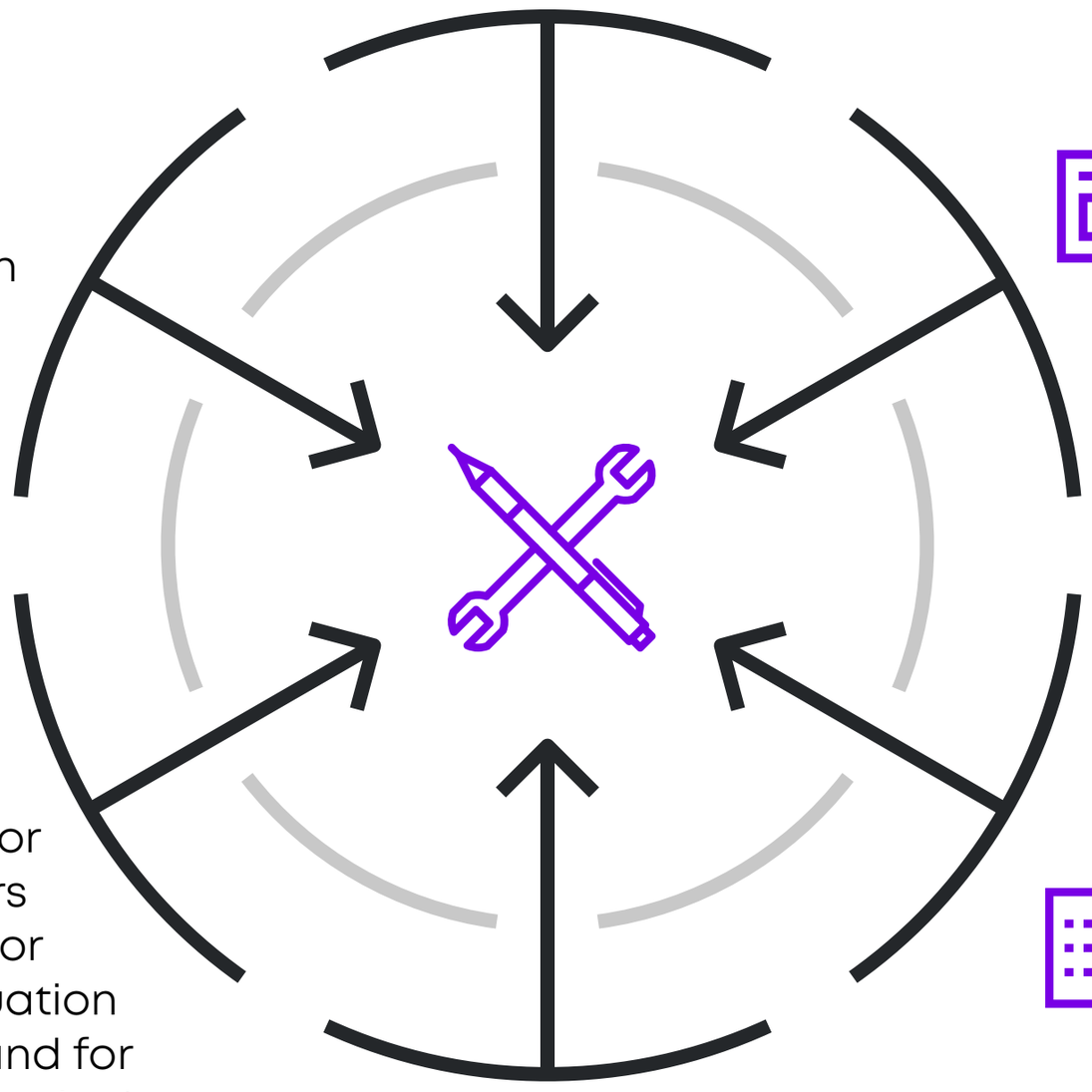
The sponsor's responsibilities include:

- Ensure that the research is conducted and data are generated, documented and reported in accordance with the protocol and good clinical practice.
- Ensure compensation and medical assistance for research participants.
- Establish contracts between the parties involved in the research.
- Appointing the investigator responsible for clinical decisions related to the research.
- Maintaining the quality and completeness of research data, even if some functions have been outsourced.
- Select the researchers and institutions that will condut the research.

General Rules

The researcher's responsibilities include:

- Having and proving the necessary qualification and experience to take responsibility for the conduct of the research.
- Ensure the rights, well-being and safety of research participants.
- Comply with good clinical and scientific practice and regulatory requirements, and conduct the research in accordance with the project approved by the CEP.
- Retain essential research data and documents for a period of 5 years after completion or formal discontinuation of the research, and for a period of 10 years in the case of advanced therapy products.
- Submit research documents, including any amendments, to the CEP for approval.
- Ensure clinical follow-up of the research participants during the conduct of the study and after its completion, under the conditions defined in the approved protocol.



General Rules

- **may or may not authorize** the storage of their biological material for other research, free of charge.
- **have the right to be informed** of the potential benefits and risks associated with the disposal of their biological material, as well as to have access to the information associated with their material.

- **may be transferred** to another biorepository or biobank, located in the country or abroad, by means of a Biological Material Transfer Agreement ("TTMB") and evidence of approval of the research project by the relevant ethical and regulatory bodies.

Protection and anonymity of research participants' personal data

Law No. 14.874/2024 regulates the protection and anonymity of the **personal data** of research participants. However, it also provides for the subsidiary application of Law No. 13709/2018 (LGPD).

General Rules

Vetoed provisions

With regards to the text approved by the Brazilian Senate, Law No. 14.874/2024 was sanctioned with two vetoes:

(i) the need to notify the Public Prosecutor's Office of the participation of a member of an indigenous group in research, and

(ii) the possibility of interrupting the supply of the experimental medicine to the research participant 5 (five) years after the commercial availability of the experimental medicine in Brazil.

The maintenance or repeal of these vetoes is still pending analysis by the National Congress.

Regulatory updates following Law No. 14.874/2024:

- **December 2, 2024:** Anvisa publishes (i) **RDC No. 945/2024**, which updates the guidelines and procedures for conducting clinical trials in the country for the subsequent registration of medicines; and (ii) **Normative Instruction No. 338/2024**, which regulates the optimized analysis procedures of clinical trial through reliance and risk and complexity assessment.

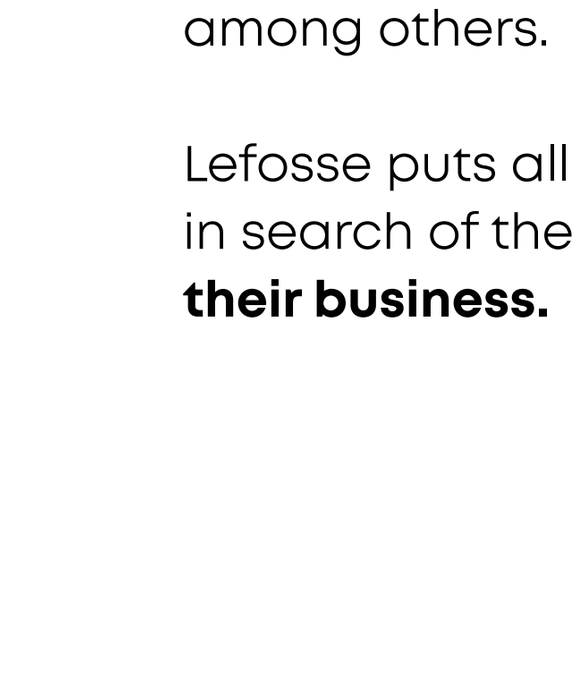
- **January 21, 2025:** The Ministry of Health and the National Health Council issued **Resolution CNS No. 738/2024**, which regulates the use of databases for scientific research involving human subjects.

About us

Our Life Sciences & Healthcare practice focuses on business sectors with high potential for growth and full of legal challenges: human and animal health.

The firm has **highly specialized professionals** in these sectors, with a focus on in a **multidisciplinary practice,** which covers the most diverse areas of law, such as regulatory, corporate, consumer, civil and criminal litigation, contracts, intellectual property, labor, tax, among others.

Lefosse puts all its practices at the service of the client, in search of the **most appropriate legal solutions for their business.**



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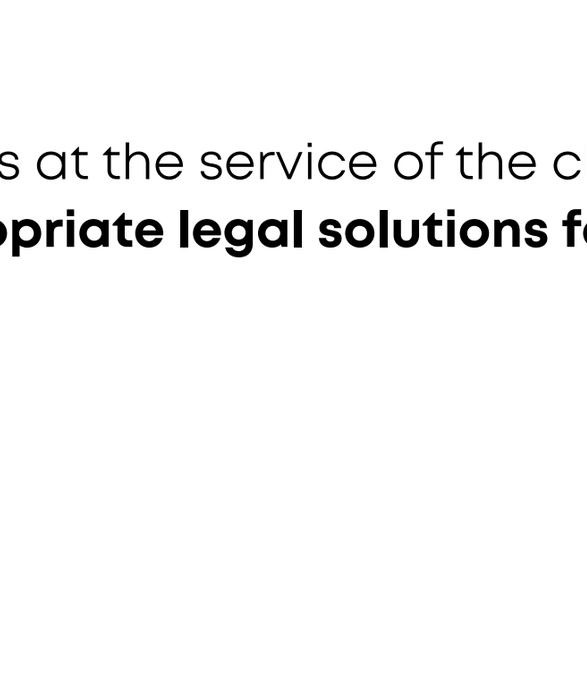

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