LAW NO. 14,874 OF 28 MAY 2024

Provides for research involving humans and establishes the Brazilian System of Ethics in Research involving Humans.

THE PRESIDENT OF THE REPUBLIC I hereby make it known that the National Congress decrees and I hereby sanction the following Law:

CHAPTER I

GENERAL PROVISIONS

Article 1. This Law establishes principles, guidelines, and rules for conducting research with humans by public or private institutions and institutes the Brazilian System of Ethics in Research with Humans.

Article 2. For the purposes of this Law, the following definitions are considered:

I – direct access: permission that an agent or institution authorized under this Law has to examine, analyze, verify, and reproduce research records and reports, upon the commitment to respect the secrecy and confidentiality of the data to which they have access;

II – consent: agreement of the child, adolescent or legally incapacitated individual to voluntarily participate in the research, after having been informed and clarified about all relevant aspects of their participation, to the extent of their capacity for understanding and in accordance with their singularities, without prejudice to the necessary consent of their legal guardians;

III – audit: systematic and independent examination of research-related activities and documents to determine whether they were carried out and whether the data were recorded, analyzed, and accurately reported in accordance with the research protocol, Standard Operating Procedures (SOPs), good practices, and other requirements set forth in regulations;

IV – health authority: entity that holds the authority to regulate, control, and inspect products and services that involve a risk to public health, pursuant to Article 8 of Law No. 9,782 of 26 January 1999;

V – biobank: organized collection, without commercial purposes, of human biological material and associated information, collected and stored for research purposes, in accordance with regulations or predefined technical, ethical, and operational standards, under the responsibility and management of a public or private institution;

VI – biorepository: organized collection, without commercial purposes, of human biological material and associated information, collected and stored for the purposes of a specific research project, in accordance with regulations or predefined technical, ethical, and operational standards, under the responsibility of a public or private institution and management of the researcher;

VII – Good Clinical Practices (GCPs): standard defined in regulations, in accordance with international standards and best practices, for planning, conducting, carrying out, monitoring, auditing, recording, analyzing, and reporting research, with a view to ensuring the credibility and validity of data and results, as well as protecting the rights, integrity, and confidentiality of the identity of research participants;

VIII – researcher or investigator's brochure: compilation of clinical and non-clinical data related to the investigational product relevant to the clinical monitoring of participants during the conduct of the research;

IX – research center: place where research-related activities are conducted;

X – Research Ethics Committee (REC): a collegiate body linked to the institution conducting the research, whether public or private, with an interdisciplinary composition, consisting of members from the medical, scientific, and non-scientific areas, with an advisory and deliberative nature, which acts independently and autonomously to ensure the protection of the rights, safety, and well-being of research participants, before and during the research, through analysis, review and ethical approval of research protocols and their amendments, as well as the methods and materials to be used to obtain and document the free and informed consent of research participants;

XI – licensed research ethics committee: a collegiate body defined in item X that has been accredited, in the form of regulation, by the Brazilian research ethics body, provided for in item XXVI, to analyze low and moderate risk research;

XII – accredited research ethics committee: a collegiate body defined in item X that, in addition to being licensed, has been accredited, in the form of regulation, by the Brazilian research ethics body, provided for in item XXVI, for the analysis of high-risk research, and may also perform analysis of low- and moderate-risk research;

XIII – free and informed consent: manifestation of the individual, or their legal representative, by signing a free and informed consent form, of their willingness to voluntarily participate in the research, after having been informed and clarified about all aspects relevant to the decision-making regarding their participation;

XIV – research contract: written agreement, dated and signed between 2 (two) or more parties involved, which defines any provisions regarding the delegation and distribution of tasks and obligations regarding the conduct of the research and, when applicable, the financial aspects, with the use of the protocol as the basis for the agreement being permitted;

XV – source data: information on clinical results, observations, or activities contained in the original records and in the certified copies of original records of a study, necessary for its reconstruction and evaluation;

XVI – deviation from the clinical trial protocol: any failure to comply with the procedures or requirements defined in the approved version of the clinical trial protocol, without relevant implications for the integrity of the trial, the quality of the data, or the rights and safety of the participants in the clinical trial;

XVII – medical device: any instrument, apparatus, equipment, implant, *in vitro* diagnostic device, software, material, or other article, intended by the manufacturer to be used, alone or in combination, in humans, for any of the following medical purposes:

a) diagnosis, prevention, monitoring, treatment, mitigation, or relief of a disease;

b) diagnosis, monitoring, treatment, or repair of an injury or disability;

c) investigation, replacement, alteration of anatomy or of a physiological or pathological state or process;

d) support or sustainment of life;

e) control of or support to conception;

f) provision of information through *in vitro* examination of samples from the human body, including organ and tissue donations;

g) exercise of an action not achievable in the human body by pharmacological, immunological, or metabolic means, but which can be aided in its intended action by such means;

XVIII – experimental medical device: a medical device whose clinical performance, efficacy, or safety is being evaluated in a clinical trial;

XIX – source document: original documents, data, and records, such as hospital records, clinical charts, medical records, laboratory data, memos, patient diaries or assessment checklists, pharmacy dispensing records, data recorded from automated instruments, certified copies or transcripts after verification as accurate copies, microfiche, photographic negatives, microfilms or magnetic media, X-rays, and records kept in the pharmacy, laboratories, and departments involved in the research, or similar documents;

XX – amendment: written description of one or more changes to the research protocol, with due justification for the change;

XXI – clinical trial: experimental clinical research with one or more humans carried out to evaluate the safety, clinical performance, or efficacy of a medical device, experimental medicinal product, or advanced therapy;

XXII – adverse event: any unfavorable medical occurrence, related or not to the investigational product, in a patient or research participant during its performance;

XXIII – serious adverse event: any adverse event that results in death, risk of death, situations that require hospitalization or prolonged hospitalization, significant disability, congenital anomaly, or clinically significant event;

XXIV – inspection: act of a regulatory authority that consists of conducting an official review of documents, facilities, records, and any other resources that are considered by the authority to be related to the clinical trial and that may be located at the research center, on the premises of the sponsor, or the Clinical Research Representative Organization (CRO), or in other establishments considered appropriate by the regulatory authorities;

XXV – research ethics review body: interdisciplinary collegiate body competent to carry out the ethical analysis of research protocols involving humans;

XXVI – Brazilian body for ethics in research: an interdisciplinary and independent collegiate body, part of the Ministry of Health, under the coordination of the technical area responsible for the field of science and technology, with a normative, consultative, deliberative, and educational nature, competent to regulate, monitor, and ethically control research, with a view to protecting the integrity and dignity of research participants, and to contribute to the development of research within ethical standards;

XXVII – experimental medicinal product: a pharmaceutical product tested or used as an object of study in a clinical trial, including a product granted marketing authorization, to be prepared in terms of the pharmaceutical formula or packaging in a manner other than that authorized by the competent body, or to be used for an indication not yet authorized or to obtain more information about the form already authorized by the competent body;

XXVIII – monitor: a qualified professional, designated by the sponsor or by the Clinical Research Representative Organization (CRO) and responsible for monitoring the research, who must act in accordance with the SOPs, good clinical practices, and applicable regulatory requirements;

XXIX – Clinical Research Representative Organization (CRO): a legal entity or organization contracted by a sponsor to perform one or more tasks and functions related to clinical research;

XXX – research participant: an individual who, freely and with informed consent, or with the clarification and authorization of his/her legal guardian, voluntarily participates in the research;

XXXI – sponsor: an individual or legal entity, either public or private, that supports research through financing, infrastructure, human resources, or institutional support;

XXXII – scientific, technological, or innovation research involving humans: research that, individually or collectively, has direct interaction with the human being, without the purpose of marketing authorization of the investigational product;

XXXIII – clinical research with humans: set of scientific procedures developed systematically with humans with a view to:

a) evaluating the action, safety, and efficacy of medicines, products, techniques, procedures, medical devices, or health care, for therapeutic, preventive, or diagnostic purposes;

b) verifying the distribution of risk factors, diseases, or injuries in the population;

c) evaluating the effects of factors or conditions on health;

XXXIV – research with humans: research that, individually or collectively, has humans as participants, in whole or in part, and involves them directly or indirectly, including the management of their data, information, or biological material;

XXXV – multicenter research: research carried out in different study centers by more than one researcher and that follows a single protocol;

XXXVI – researcher or investigator: person responsible for conducting the research in an institution or research center and jointly responsible for the integrity and well-being of the research participants;

XXXVII – coordinating researcher or coordinating investigator: person responsible for coordinating the research and researchers from different centers participating in multicenter research and co-responsible for the integrity and well-being of the research participants;

XXXVIII – placebo: formulation without pharmacological effect, or a simulated procedure, used in control groups of clinical trials and intended for comparison with the intervention under experimentation;

XXXIX – post-study supply plan: document prepared by the sponsor and submitted to ethical analysis, with the justification for the supply or non-supply of the experimental medicinal product after the end of the clinical trial;

XL – Standard Operating Procedures (SOPs): detailed, written operating instructions, which aim to provide uniformity of procedures;

XLI – comparison product: product granted marketing authorization or placebo used in the control group of a clinical trial to allow comparison of its results with those of the group that received the intervention under experimentation;

XLII – experimental advanced therapy product: a special type of complex medicinal product used in a clinical trial, consisting of cells that have undergone extensive manipulation and/or that perform a function different from the original, or that consists of a recombinant human gene or contains a recombinant human gene, with the purpose of obtaining therapeutic, preventive, or diagnostic properties, not yet granted marketing authorization or that is in the testing phase for indication of use not yet approved by the competent health authority;

XLIII – investigational product: experimental medicinal product, placebo, active comparator, or any other product used in the clinical trial;

XLIV – post-study supply program: a document prepared by the sponsor and submitted to ethical analysis, with a detailed description of the strategy for free supply of the experimental product after the end of the clinical trial;

XLV – research project: a document that presents the central ideas of the research, with a detailed description of the actions and procedures that will be developed during the investigation;

XLVI – research protocol: a document that describes the objectives, design, methodology, statistical considerations, organization of the study, context and rationale, among other elements;

XLVII – prior material provision: financial compensation for expenses of the participant and their companions, when necessary, carried out prior to their participation in the research;

XLVIII – adverse reaction: any harmful and unintentional response to any dose of the investigational product or to the new indication of that product;

XLIX – unexpected adverse reaction: adverse reaction of a nature, severity, specificity, or clinical outcome not consistent with the information available about the investigational product, according to the data in the researcher's brochure;

L – research report: written document with the results of the research, which necessarily contains an integrated description and analysis of the research data, including clinical and statistical data;

LI – representative of the research participant: person capable of expressing the points of view and interests of individuals participating in the research;

LII – reimbursement: material compensation, exclusively for expenses of the participant and their companions, when necessary, such as expenses with transportation and food;

LIII – Free and Informed Consent Form (FICF): document in which the free and informed consent of the research participant, or their legal guardian, is explicitly given, in writing, with all the necessary information, in clear and objective language, easy to understand, for complete clarification about the research in which they intend to participate;

LIV – impartial witness: an individual not involved in the research and not linked to a person directly involved in it who accompanies the informed consent process in cases where the research participant, or his/her legal representative, is not able to read;

LV – violation of the research protocol: deviation from the protocol that may compromise the quality of the data, the integrity of the research or the safety or rights of the research participants;

LVI – vulnerability: a condition in which a person or group of people has reduced capacity to make decisions and to oppose resistance in the research situation, due to individual, psychological, economic, cultural, social, or political factors, observing, in any case, the consent described for situations of vulnerability.

Article 3. The research must meet the ethical and scientific requirements applicable to research with humans, especially:

I – respect for the rights, dignity, safety, and well-being of the research participant, which must prevail over the interests of science and society;

II – basis in a favorable assessment of the risk-benefit ratio for the research participant and for society;

III – solid scientific basis and description in protocol;

IV – conduct in accordance with the protocol approved by the REC;

V – guarantee of competence and technical and academic qualification of the professionals involved in conducting the research;

VI – guarantee of voluntary participation, upon free and informed consent of the research participant;

VII – respect for the privacy of the research participant and the rules of confidentiality of their data, ensuring the preservation of the confidentiality of their identity;

VIII – provision of necessary care in cases involving intervention;

IX – adoption of procedures that ensure the quality of the technical aspects involved and the scientific validity of the research;

X – conduct of the research in full compatibility with good clinical practices.

Sole paragraph. In addition to the provisions in the caption of this article, in the case of a clinical trial, the research shall meet the following requirements:

I – availability of clinical and non-clinical information about the investigational product, to support the conduct of the research;

II – guarantee of medical care and medical decision-making in the interest of the research participant;

III – continuous assessment of the need to adapt or suspend the ongoing study as soon as the significant superiority of one intervention over another is confirmed;

IV – production, handling, and storage of the investigational products in accordance with good manufacturing practice standards;

V – record in public databases;

VI – guarantee of participation of representatives of both sexes and of racial segments that constitute society, when essential for the research and when it does not generate any type of harm to its progress, requiring in these cases the application of technical-scientific criteria based on the object of the research.

Article 4. The research protocol and contract shall comply with the provisions of this Law and the regulation.

CHAPTER II

BRAZILIAN SYSTEM OF ETHICS IN RESEARCH WITH HUMANS

Section I

Ethical Analysis

Article 5. The Brazilian System of Ethics in Research with Humans is hereby established, to be regulated by an act of the Executive Branch, which is divided into:

I – Brazilian body of ethics in research;

II – body of ethical analysis in research, represented by the RECs.

Article 6. Research with humans shall be subject to prior ethical analysis, to be carried out by the body of ethical analysis in research, in order to guarantee the dignity, safety, and well-being of the participant.

Article 7. The ethical analysis of research with humans shall be carried out as defined in this Law and in accordance with the following guidelines:

I – protection of the dignity, safety, and well-being of the research participant;

II – encouragement of technical-scientific development;

III – independence, transparency, and publicity;

IV – equality in the application of criteria and procedures for analyzing research projects, according to the risk-benefit ratio inferred from their protocols;

V – efficiency and agility in the analysis and issuing of opinions;

VI – multidisciplinarity;

VII – social control, with the participation of a representative of the research participants;

VIII – respect for good clinical practices.

Sole paragraph. Any member of a REC who has any interest in the research or who maintains a relationship with the sponsor or researchers will be prevented from participating in the deliberation regarding the research in which he or she is involved.

Section II

Brazilian Research Ethics Body

Article 8. The following duties are incumbent upon the Brazilian research ethics body, as provided for in item I of Article 5:

I – to issue regulatory standards on research ethics;

II – to evaluate the effectiveness of the Brazilian System of Ethics in Research with Humans;

III – to accredit and license the RECs, so that they can perform the function of ethical analysis in research, according to the degree of risk involved;

IV – to monitor, support, and supervise the RECs in relation to the analysis of research protocols and compliance with the relevant standards;

V – to promote and support the training of the members of the RECs, with special emphasis on ethical and methodological aspects;

VI – to act as an appeals body for the decisions handed down by the RECs.

Section III

Body of Ethical Analysis in Research

Article 9. The REC, which represents the body of ethical analysis in research, provided for in item II of Article 5, shall meet the following conditions, among others set forth in the regulations:

I – be composed of an interdisciplinary team, in the medical, scientific and non-scientific areas, in order to ensure that, as a whole, the members have the necessary qualifications and experience to analyze all aspects inherent to the research, including medical, scientific, ethical aspects and those related to good clinical practices;

II – be licensed by the Brazilian research ethics body;

III – have regular operations;

IV – have adequate infrastructure to carry out its activities;

V – keep a list of its members publicly available, with their respective professional qualifications;

VI – have a document describing the operational procedures adopted and keep written records of its activities and meetings;

VII – have in its composition 1 (one) representative of the research participants.

Paragraph 1. Depending on the degree of risk involved in the research, in accordance with the regulations, the role of the research ethics review body shall be exercised:

I – by a REC licensed or accredited by the Brazilian research ethics body, in the case of low- or moderate-risk research;

II – by a REC accredited by the Brazilian research ethics body, in the case of high-risk research.

Paragraph 2. In the case of research involving a special group, to be established by the regulations, the REC will ensure, whenever possible, in the discussion on the protocol, the participation of:

I – 1 (one) representative of the special group, as an *ad hoc* member;

II – 1 (one) consultant familiar with the language, customs, and traditions of the specific community, when the research involves that community.

Paragraph 3. The deliberation on the ethical adequacy of the research will take place in a previously scheduled meeting, which must have a minimum quorum, as defined in the REC's internal regulations.

Paragraph 4. Only full members of the REC may issue opinions and deliberate on the ethical suitability of research submitted to the committee.

Paragraph 5. REC members may invite external experts and representatives of vulnerable groups to issue opinions on specific issues related to research projects, but they will not have the right to vote.

Paragraph 6. Once duly licensed or accredited, RECs have complete autonomy to issue their opinions, in compliance with good clinical practices.

Article 10. The institution hosting the REC shall promote and support the training of its committee members, with an emphasis on ethical and methodological aspects related to the rights of research participants.

Article 11. The REC's activities shall be subject to inspection and monitoring by the Brazilian research ethics body.

Sole paragraph. Failure by the REC to comply with the provisions of this Law shall result in cancellation of its license by the Brazilian research ethics body, in accordance with regulations.

Section IV

Responsibilities of the Research Ethics Committee

Article 12. The REC shall be responsible for:

I – ensuring the rights, safety, and well-being of research participants, especially participants in vulnerable situations;

II – considering the qualifications of the researcher for the proposed research, in accordance with his/her academic and professional curriculum and the documents requested by the board;

III – conduct the analysis of the research submitted to it and monitor its execution, observing the minimum frequency defined in the regulation, in accordance with the classification of the research and good clinical practices;

IV – request the provision of additional information to the research participants, when it is deemed indispensable for the protection of the rights, safety, and well-being of the research participants;

V – ensure that the research project and other documents adequately address relevant ethical issues and meet the applicable regulatory requirements, including those related to good practices;

VI – ensure that adequate means are provided to obtain the consent of the research participant or his/her legal representative;

VII – ensure that the information regarding reimbursement or prior material provision to the research participant is clearly specified in the FICF, including the forms, amounts, and respective frequency.

Section V

Research Ethics Analysis Process

Article 13. The research ethics analysis process shall be instructed with the information and documents established in specific regulations.

Sole paragraph. The REC will keep all documents related to the project on file for a period of 5 (five) years after the end of the research, with digital archiving being permitted.

Article 14. The ethical analysis of the research, carried out by the REC, with the issuance of the opinion, may not exceed the period of 30 (thirty) business days from the date of acceptance of the entire research documents, and this acceptance, or its rejection, must be made by the REC within 10 (ten) business days from the date of submission.

Paragraph 1. Before issuing the opinion, the REC may request additional information or documents from the researcher or research sponsor or make adjustments to the research documentation, with the suspension of the period provided for in the caption of this article for a maximum of 20 (twenty) business days.

Paragraph 2. The researcher will have a period of 10 (ten) business days, extendable for the same period upon justification, to meet the demands requested by the REC, and the study analysis process may be canceled in case of non-compliance with the deadline.

Paragraph 3. At the discretion of the REC, the researcher may participate in the collegiate meeting to provide clarifications about the research, but his/her presence at the time of the final decision is prohibited.

Paragraph 4. The opinion referred to in the caption of this article will conclude, with reasoned grounds, for:

I – approval of the research;

II – non-approval of the research; or

III – suspension, when the approved research, already in progress, needs to be interrupted for safety reasons.

Paragraph 5. The decision contained in the REC's opinion may be appealed, in the first instance, within 30 (thirty) business days, to the REC itself that issued the opinion and, in the second and last instance, within 30 (thirty) business days, to the Brazilian research ethics authority.

Paragraph 6. The appeals provided for in Paragraph 5 shall be decided by the competent authority within a period of up to 30 (thirty) business days.

Paragraph 7. The ethical analysis of research involving more than one research center in Brazil shall be carried out by a single REC, preferably the one linked to the research coordinating center, which shall issue the opinion and notify the RECs of the other participating centers of its decision.

Paragraph 8. All documents requested by the REC shall be provided for in an act of the Executive Branch, in a regulation or in the rules of the REC itself and be relevant to the subject matter being analyzed.

Article 15. Research of strategic interest to the Unified Health System (SUS, in Portuguese) and relevant to responding to the public health emergency shall be given priority in the ethical analysis and shall be subject to special analysis procedures, including deadlines, in accordance with the regulation.

Sole paragraph. The opinion regarding the research specified in the caption of this article will be issued within a period of no more than 15 (fifteen) business days from the date of receipt of the research documents.

Article 16. After the start of the research, if there is a need for a change that interferes with the risk-benefit ratio or the approved documentation, the coordinating researcher shall submit, in writing, a duly justified amendment to the research project for analysis and opinion by the REC that analyzed the research.

Paragraph 1. The change made by means of an amendment may only be implemented after approval by the REC, in accordance with the caption of this article, except when the safety of the research participant depends on its immediate implementation.

Paragraph 2. The provisions of Article 14 shall apply, where applicable, to amendments to the research project.

Article 17. All those involved in the conduct, monitoring, evaluation, or approval of the research who have direct access to its records, in order to verify compliance with the procedures and applicable legislation and the validity or integrity of the data, shall ensure the preservation of the confidentiality of the data and the anonymity of the research participant, in accordance with the legislation in force.

CHAPTER III

PROTECTION OF RESEARCH PARTICIPANTS

Section I

General Provisions

Article 18. Participation in research is subject to the express authorization of the participant, or his/her legal representative, by means of signing the FICF.

Paragraph 1. The FICF shall be written in a language that is easy to understand and shall only be valid when dated and signed by the researcher in charge and the research participant or his/her legal representative or, in the case of Paragraph 5, by an impartial witness.

Paragraph 2. The FICF referred to in the caption of this article shall be updated and submitted for review by the REC that approved the research whenever new relevant information arises that may alter the research participant's decision regarding his/her participation.

Paragraph 3. Information, whether verbal or written, regarding the research, including that contained in the FICF, may not indicate or suggest:

I – the waiver, by the research participant, of his/her rights;

II – the exemption of the researcher, the institution, the sponsor, or their agents from liability for any damages that may be caused to the research participant.

Paragraph 4. The researcher or the professional designated by him/her must fully inform the participant or his/her legal representative of the relevant aspects of the research, including the approval by the REC.

Paragraph 5. If the research participant or his/her legal representative is unable to read, an impartial witness must be present throughout the reading and clarification of the FICF, and, after the verbal consent of the participant or his/her legal representative, must date, write his/her name legibly and sign the FICF.

Paragraph 6. The inclusion of a participant in research in an emergency and without his/her prior consent will follow the provisions of the approved protocol, and the fact must be informed to the research participant or his/her legal representative at the first possible opportunity and the decision regarding his/her continued participation in the research must be obtained.

Paragraph 7. The research participant or his/her legal representative may withdraw his/her consent at any time, regardless of justification, without any burden or prejudice.

Article 19. The research will be conducted in a way that guarantees the anonymity and privacy of the participant, as well as the confidentiality of the information.

Paragraph 1. The privacy of the participant is a matter of personal privacy.

Paragraph 2. The confidentiality of the technical information of the research must be lifted when necessary for the analysis of serious adverse events.

Paragraph 3. In the event of a serious adverse event, the participant, his/her legal representatives or his/her successors may disclose details related to the former's participation in the research.

Article 20. The remuneration of the participant or the granting of any type of advantage for his/her participation in research is prohibited.

Paragraph 1. The following do not constitute remuneration or advantage for the research participant:

I – reimbursement of expenses with transportation or food or the prior provision of material;

II – other types of reimbursement required, according to the research project.

Paragraph 2. The participation of healthy individuals in phase I or bioequivalence clinical trials is exempt from the caption of this article, provided the following conditions are met:

I – the participant is included in the Brazilian registry of volunteers in bioequivalence and phase I studies, as per regulations;

II – the participant is not simultaneously involved in more than one research study;

III – in the case of research to assess the maximum tolerated dose or to assess bioavailability and bioequivalence, the research participant must observe a minimum period of 6 (six) months from the date of termination of participation in the research before being included in a new clinical trial.

Article 21. The exclusive use of placebo is only permitted when there are no proven methods of prophylaxis, diagnosis, or treatment for the disease that is the subject of the research, accordingly, and provided that the risks or harm resulting from the use of placebo do not outweigh the benefits of participating in the research.

Sole paragraph. In the case of using placebo combined with another method of prophylaxis, diagnosis, or treatment, the research participant may not be deprived of receiving the best treatment available, or that recommended in Clinical Protocols and Therapeutic Guidelines of the Ministry of Health, or, alternatively, in therapeutic protocols recommended by a medical society specialized in the area of study.

Article 22. In clinical trials, as soon as significant superiority of the experimental intervention over the comparison product or placebo is confirmed, the coordinating researcher, the independent monitoring committee, or the sponsor shall assess the need to adapt or suspend the ongoing study, in order to meet the best interests of the research participant.

Article 23. The participant shall be compensated for any damage suffered as a result of his/her participation in the research and shall receive the necessary health care related to such damage.

Sole paragraph. The sponsor shall be responsible for the compensation and care provided for in the caption of this article.

Section II

Protection of Participants in Vulnerable Situations

Article 24. In addition to the provisions of Section I of this Chapter, the inclusion of participants in vulnerable situations in research, even if circumstantially, is subject to the following conditions being met:

I – there must be an informed consent form signed by a legal representative or a judicially appointed representative, in compliance with the provisions of Article 18 of this Law;

II – the research must be essential for the population represented by the participant in a vulnerable situation, and it must not be possible to obtain data of comparable validity through the participation of adults capable of giving their consent or using other research methods.

Paragraph 1. The provisions of item I of the caption of this article shall not eliminate the need to provide information to the research participant, when possible and to the extent of their ability to understand, respecting their decision to participate, expressed through a consent form, whenever they are able to evaluate and decide on the information received.

Paragraph 2. The researcher in charge and the representative of the incapacitated person shall co-sign a communication to the Public Prosecutor's Office, informing the schedule for the incapacitated person's participation in the research.

Paragraph 3. (VETOED).

Article 25. Research with pregnant women shall be preceded by similar research with women outside the gestational period, except when the pregnancy or the unborn child is the fundamental object of the research.

Sole paragraph. The research referred to in the caption of this article shall only be permitted when the foreseeable risk to the health of the pregnant woman or the unborn child is minimal.

CHAPTER IV

RESPONSIBILITIES OF THE SPONSOR AND THE RESEARCHER

Article 26. The sponsor's responsibilities include:

I – implementing and maintaining quality assurance and quality control systems, based on the SOPs, in order to ensure that the research is conducted, and the data are generated, documented, and reported in compliance with the protocol, good clinical practices, and the requirements of the regulation;

II – establishing the contract between the parties involved in the research;

III – quality control of each stage of data processing, with a view to ensuring its reliability and correct processing;

IV – maintaining the quality and integrity of the research data, even if some or all functions have been transferred to third parties;

V – selecting the researchers and institutions executing the research, considering the qualifications necessary for conducting and supervising the research;

VI – ensuring adequate resources for conducting the research, including the cost of all expenses related to procedures, examinations, and actions to resolve adverse events;

VII – indicating a researcher to be responsible for clinical decisions related to the research, in the case of a clinical trial;

VIII – verifying that the research participant has authorized direct access to his/her data and information for purposes of monitoring, auditing, review by competent ethical entities, and inspection by regulatory agencies;

IX – prompt notification to the researcher, the executing institution, competent ethical review entities, and the health authority of discoveries that may adversely affect the safety of the research participant, compromise the conduct of the research, or affect the approval granted by the REC;

X – in the case of clinical trials, the issuance of reports on adverse reactions to the medicinal product or experimental products considered serious or unexpected, which must be reported to the institutions and researchers involved and to the health authority;

XI – prompt notification to the health authority of all serious or unexpected adverse events whose causality is possible, probable, or defined in relation to the investigational product;

XII – selection and training of monitors and auditors;

XIII – adequate monitoring of the research;

XIV – prompt communication to the researchers involved, the executing institution, and the health authority about the reasons for the suspension or premature termination of the research, when applicable;

XV – compensation and health care for the research participant for any damage suffered as a result of their participation in the research.

Paragraph 1. The sponsor, who is ultimately responsible for the research, may delegate the execution of certain functions to the CROs, which will assume shared responsibility for the purpose of the delegation.

Paragraph 2. Whenever possible, an independent data monitoring committee should be set up to periodically assess the progress of the research, safety data, and critical points of efficacy, and recommend to the sponsor whether to continue, modify, or discontinue a research study.

Paragraph 3. The institutions and organizations involved in the research shall be jointly responsible for its conduct and shall provide full assistance to participants regarding complications and harm resulting from the research.

Article 27. The researcher's responsibilities are:

I – to have and prove the qualifications and experience necessary to assume responsibility for the proper conduct of the research;

II – to comply with the standards of good clinical and scientific practices and regulatory requirements;

III – to submit the research documentation, including any amendments, for approval by the REC;

IV – to select qualified individuals to perform the tasks related to the research;

V – to ensure, in the case of a clinical trial, clinical monitoring of the research participants during the conduct of the study and after its completion, for the period and under the conditions defined in the protocol approved by the REC;

VI – conduct the research in compliance with the project approved by the REC;

VII – provide, when requested, direct access to the research records and documents for the monitor, the auditor, other representatives of the sponsor, the REC, the Brazilian research ethics body, and the health authority;

VIII – allow the monitoring and auditing of the research by the sponsor, as well as inspections by the health authority, the Brazilian research ethics body and the REC that approved it;

IX - submit partial reports with information on the progress of the research, annually and whenever requested, to the REC that analyzed it;

X – promptly communicate to the sponsor, the health authority, the REC, and the Brazilian research ethics body all serious or unexpected adverse events;

XI – keep stored and under its custody, in physical or digital media, the essential data and documents of the research for a period of 5 (five) years after its formal termination or discontinuation, and for a period of 10 (ten) years in the case of advanced therapy products;

XII – ensure the rights of research participants and ensure their well-being and safety.

CHAPTER V

MANUFACTURING, USE, IMPORT, AND EXPORT OF GOODS OR PRODUCTS FOR CLINICAL RESEARCH PURPOSES INVOLVING HUMANS

Article 28. For clinical trial purposes, the manufacturing, use, import, and export of medicines, medical products and devices, and experimental advanced therapy products must be authorized by the health authority, in accordance with regulations.

Paragraph 1. The use of the products referred to in the caption of this article must be carried out in the manner authorized by the health authority, in accordance with the approved research protocol.

Paragraph 2. For clinical trial purposes, the export and import of experimental advanced therapy products must be authorized by the regulatory authorities, in accordance with specific regulations.

Article 29. Medicines, products, medical devices, and experimental advanced therapy products will be packaged, stored, and discarded in accordance with regulations.

CHAPTER VI

CONTINUITY OF POST-CLINICAL TRIAL TREATMENT

Article 30. Before the start of the clinical trial, the sponsor and the researcher shall submit a post-study access plan to the REC, presenting and justifying whether there is a need to provide the experimental medicinal product free of charge after the end of the clinical trial to participants who need it.

Paragraph 1. If there is a need to provide the medicinal product after the clinical trial, a post-study supply program must be drawn up, in accordance with the regulations.

Paragraph 2. The post-study supply program must ensure the continuity of the participant's safety monitoring, to guarantee the receipt of the experimental treatment after the end of the clinical trial, for a set period.

Paragraph 3. The post-study supply program must be initiated only after regulatory approval, the request for which must be submitted in a timely manner so that the research participant can transition to the post-study period without prejudice to the continuity of the treatment.

Article 31. At the end of the clinical trial, an assessment of the need for continuation of the experimental treatment for each participant must be carried out individually.

Paragraph 1. The assessment referred to in the caption of this article shall be carried out by the researcher, after hearing the sponsor and the research participant, in accordance with the regulations.

Paragraph 2. The free provision of the experimental medicinal product after the clinical trial must be carried out whenever it is considered the best therapy or treatment for the clinical condition of the research participant and presents a more favorable risk-benefit ratio compared to other available treatments.

Paragraph 3. The free provision of the experimental medicinal product after the clinical trial, when necessary, shall be guaranteed after the end of individual participation through a post-study provision program, to which the participant must automatically migrate.

Paragraph 4. In cases where maintenance of treatment with an experimental medicinal product is necessary after the end of the clinical trial, the sponsor shall be responsible for providing the medicinal product.

Article 32. The assessment of the need for continued provision of the experimental medicinal product after the clinical trial must be carried out in accordance with the following criteria:

I – the severity of the disease and its threat to the participant's life;

II – the availability of satisfactory therapeutic alternatives for the treatment of the research participant, considering their location;

III – whether the experimental medicinal product addresses an unmet clinical need;

IV – whether the evidence of benefit to the participant outweighs the evidence of risk using the experimental medicinal product.

Article 33. The free provision of the experimental medicinal product within the scope of the post-study provision program may be interrupted, upon submission of justification to the REC, for assessment, only in one of the following situations:

I – decision of the research participant himself or, when he cannot validly express his will, by the criteria specified in Article 18 of this Law;

II – cure of the disease or health problem targeted by the clinical trial, or introduction of a satisfactory therapeutic alternative, a fact duly documented by the researcher;

III – lack of benefit from continued use of the experimental medicinal product to the research participant, considering the risk-benefit ratio outside the context of the clinical trial or the emergence of new evidence of risks related to the safety profile of the experimental medicinal product, a fact duly documented by the researcher;

IV – occurrence of an adverse reaction that, at the discretion of the researcher, makes it impossible to continue using the experimental medicinal product, even in the face of possible benefits;

V – impossibility of obtaining or manufacturing the experimental medicinal product due to technical or safety issues, duly justified, and provided that the sponsor provides an equivalent or superior therapeutic alternative available on the market;

VI – (VETOED);

VII – availability of the experimental medicinal product in the public health network.

Article 34. The researcher shall be responsible for requesting the sponsor to begin providing the experimental medicinal product to the research participant after the clinical trial, in accordance with the criteria defined in this Law.

Paragraph 1. The sponsor shall guarantee the research participants the free provision of the experimental medicinal product after the clinical trial whenever the researcher considers it to be the best treatment for the clinical condition of the research participant and presents a more favorable risk-benefit ratio compared to other available treatments, in accordance with this Law and regulations.

Paragraph 2. The free post-study provision of the experimental medicinal product referred to in Paragraph 1 of this article will be guaranteed after the end of individual participation, through a post-study access program, and the participant must automatically migrate to this new protocol.

Paragraph 3. To comply with the provisions of this article, the import and dispensing of experimental medicinal products during the post-study access program must be previously authorized by the competent health authority, in accordance with the regulations.

Article 35. The researcher, the sponsor, and the institution where the research took place must make plans to transition participants who continue to require health care or measures, after the end of the clinical trial, to the appropriate health services, as available, in accordance with this Law, provided that such care is not related to reactions arising from the study itself.

Paragraph 1. The planned transition of participants who have received the free provision of medication or treatment after the clinical trial to other available means of provision must also be considered, if necessary.

Paragraph 2. In the event of reactions resulting from the study itself, the sponsor must ensure appropriate and necessary health care or measures for the research participant.

Article 36. The use of an experimental medicinal product during a post-study supply program shall comply with the standards established in regulations.

Article 37. The provisions of this Chapter shall apply to medical products and devices and to experimental advanced therapy products subject to clinical trials, where applicable.

CHAPTER VII

STORAGE AND USE OF DATA AND HUMAN BIOLOGICAL MATERIAL

Article 38. Studies with biological material of human origin must avoid discrimination and stigmatization of an individual, family or group, regardless of the benefits achieved through the research.

Article 39. For the purposes of this Law, consent for the disposal of human biological material and its data, in life or *postmortem*, must be formalized by means of a FICF and must be given free of charge, altruistically and in an informed manner, in compliance with the provisions of Law No. 13,709 of 14 August 2018 (General Law on the Protection of Personal Data).

Sole paragraph. The *postmortem* disposal shall comply with the provisions of Law No. 8,501 of 30 November 1992 and Article 14 of Law No. 10,406 of 10 January 2002 (Civil Code).

Article 40. The rights of the research participant are:

I – to be duly informed and clarified, in a clear and objective manner, whenever he/she deems it pertinent, about the object and the potential benefits and risks inherent in the disposal of his/her biological material;

II – to have their health and physical and mental integrity protected during the biological material collection procedures;

III – to withdraw at any time the consent for the storage and use of stored human biological material, in writing and signed, without charge or prejudice, with right to have the samples returned;

IV – to have access, at any time, without charge or prejudice, to information about the purposes of storage, including the names of the technical and institutional managers, the potential risks and benefits, the guarantees of conservation quality and the integrity of their biological material;

V – to have access, at any time, without charge or prejudice, to information associated with their biological material and to be informed and guided by the researchers responsible for findings when the implications of this information may cause harm to their health, including genetic counseling when applicable;

VI – to have the privacy and confidentiality of their personal information guaranteed;

VII – to be promptly informed about the dissolution of the repository in which their biological material is stored;

VIII – to be promptly informed about the transfer, loss, alteration, or disposal of their biological material;

IX – to designate legal representatives who may consent to the use and disposal of their biological material and have access to such materials and their associated information in the event of death or incapacitating condition;

X – to be informed, at the time of signing the FICF, about the possibility of providing or not providing consent for possible future uses of their data and biological material in research;

XI – to be informed, at the time of signing the FICF, about the possibility of authorizing or not the sending of their data and biological material to a research center located outside Brazil.

Sole paragraph. All rights of the research participant must be included in the FICF.

Article 41. The storage period of human biological material in a biobank is indefinite.

Article 42. The storage period of human biological material in a biorepository must be in accordance with the schedule provided for in the approved research project.

Article 43. The human biological material stored in a biobank or biorepository belongs to the research participant, provided that its custody is under institutional responsibility.

Article 44. The management of the stored human biological material shall be the responsibility of:

I – the institution to which it is linked, in the case of storage in a biobank;

II – the researcher coordinating the research, in the case of storage in a biorepository.

Sole paragraph. At the end of the validity of the research project referred to in the caption of this article, the human biological material may:

I – remain stored, if in compliance with the legislation and the applicable and current ethical and regulatory standards;

II – be transferred to another biorepository or biobank; or

III – be discarded.

Article 45. Biological material and research data shall be used exclusively for the purpose provided for in the respective project, except when, in the FICF, express authorization is granted for them to be used in future research, for exclusively scientific purposes, provided that the provisions of this Law and the regulation are observed.

Article 46. Human biological material and its associated information stored in a biorepository may be formally transferred to another biorepository or biobank, in accordance with the provisions of Article 45 of this Law and other current regulations.

Article 47. Human biological material and its associated information stored in a biobank may be formally transferred to another biobank, in accordance with the provisions of Article 45 of this Law and other current regulations.

Article 48. Human biological material and its associated information may be formally transferred to researchers, in accordance with the provisions of Article 45 of this Law and other current regulations, by signing a Biological Material Transfer Agreement (TTMB, in Portuguese) and presenting proof of approval of the research project by the relevant ethical and regulatory bodies.

Paragraph 1. The samples and components of the human biological material and associated information that have been transferred may not be passed on to third parties by the initial recipient institution, except when a new TTMB is signed between the original sending institution and the new receiving institution.

Paragraph 2. The transfer of human biological material from the sending institution to the receiving institution must follow current health regulations, without prejudice to specific regulations for each type of biological material and the mode of transportation.

Paragraph 3. The shipment and storage of human biological material to a research center located outside Brazil are the responsibility of the sponsor, subject to the following conditions:

I – compliance with national and international health legislation on shipment and storage of biological material;

II – guarantee of access to and use of biological material and its data for scientific purposes by researchers and Brazilian institutions;

III – compliance with Brazilian legislation, especially regarding the prohibition of patenting and commercialization of biological material.

Article 49. Human biological material stored in a biobank or biorepository, considered starting material, and associated information are not subject to protection of rights relating to intellectual property, and their purchase, sale, or any other type of commercialization by individuals or legal entities, whether occasional or permanent, in disagreement with the legislation and standards in force, is expressly prohibited.

Sole paragraph. The charging of amounts for the purpose of recovering costs with inputs, materials, laboratory tests, processing, storage, transportation, and fees is not considered commercialization.

Article 50. The place where biological material is used and stored must have a security system that ensures the confidentiality of the identity of the research participant and data confidentiality.

Article 51. Research data will be stored by the institution carrying out the research, under the responsibility of the researcher, for a period of 5 (five) years after the end or discontinuation of the research.

Paragraph 1. The institution carrying out the research must establish mechanisms to protect the confidentiality of the information linked to the data, sharing only anonymous or encoded data, and the key to the code must remain with the data manager, in compliance with the provisions of Law No. 12,527 of 18 November 2011 (Law on Access to Information), and Law No. 13,709 of 14 August 2018 (General Law on the Protection of Personal Data).

Paragraph 2. The storage of data in a research center located outside Brazil is the responsibility of the institution carrying out the research.

Paragraph 3. The alteration in the data storage period established in the caption of this article may be authorized by the REC, upon request by the researcher.

Paragraph 4. In the case of research involving advanced therapy products, the term referred to in the caption of this article shall be 10 (ten) years.

CHAPTER VIII

ADVERTISING, TRANSPARENCY, AND MONITORING OF RESEARCH

Article 52. The research shall be registered with the Brazilian research ethics body and its data shall be updated on a publicly accessible website, in accordance with the regulations.

Article 53. The coordinating researcher shall send an annual report on the progress of the research to the REC that approved it.

Article 54. The researcher shall inform the research participants, using appropriate means and in clear language accessible to laypeople, of the results of the research in which they have participated.

Article 55. Serious adverse events occurring during the research shall be subject to mandatory reporting to the REC that approved the research.

Sole paragraph. In the case of clinical trials for the purpose of marketing authorization of products subject to health assessment, adverse reactions or events occurring during the conduct of these studies must also be reported to the health authority.

Article 56. Violations of the research protocol must be reported to the RECs and the health authority that approved the research.

Article 57. The discontinuation of ongoing research, whether temporary or permanent, must be reported to the REC that approved it, and the coordinating researcher must submit, together with the notification of discontinuation, the technical and scientific justifications that supported the decision, in addition to submitting to that collegiate body, within 30 (thirty) business days, a detailed report with the results obtained up to the time of interruption.

Paragraph 1. In the case of a clinical trial, in addition to the documentation specified in the caption of this article, the coordinating researcher and the sponsor must submit a monitoring and assistance plan necessary for the participants of the discontinued research.

Paragraph 2. The discontinuation of research for reasons that are not relevant, according to the assessment of the competent REC, shall be considered an ethical violation and shall subject the violator to the sanctions provided for in Article 60 of this Law.

CHAPTER IX

FINAL PROVISIONS

Article 58. In order to regulate the caption and Paragraph 1 of Article 218 of the Federal Constitution, the health analysis related to the primary petitions for clinical trials with humans, for the purposes of marketing authorization of the investigational product, may not exceed the period of 90 (ninety) business days.

Paragraph 1. If there is no response from the health authority within the period provided for in the caption of this article, after regular receipt of the primary petition for the clinical trial, clinical development may be initiated, provided that it contains the pertinent ethical approvals.

Paragraph 2. The health authority may request additional clarifications and documents only once, a requirement that shall give rise to the suspension of the analysis period, its interruption being prohibited.

Paragraph 3. Specific regulations shall provide for compliance with the deadline and requirements set forth in this article.

Paragraph 4. The health authority is authorized to conduct GCP inspections in clinical research centers, sponsors, and CROs, in accordance with the regulations.

Article 59. Conducting research with humans in non-compliance with the provisions of this Law constitutes an ethical infraction and subjects the offender to the disciplinary sanctions provided for in the legislation of the professional council to which he/she is affiliated, without prejudice to applicable civil and criminal sanctions.

Sole paragraph. For the purposes of applying the disciplinary sanctions referred to in the caption of this article, the competent professional councils shall be notified, by the REC or by the Brazilian research ethics body, of the ethical infraction committed.

Article 60. Failure to comply with the provisions of articles 26, 27, 35, 42, 51, and 55 of this Law and failure to comply with the GCP standards, as per the regulation, constitutes a health infraction and subjects the offender to the penalties provided for in Law No. 6,437 of 20 August

1977 and in specific health regulations, without prejudice to applicable civil and criminal sanctions.

Article 61. The protection and anonymity of personal data of research participants are regulated by this Law, applied subsidiarily to Law No. 13,709 of 14 August 2018 (General Law on the Protection of Personal Data).

Article 62. The provisions of this Law shall apply to medical products and devices and to experimental advanced therapy products, where applicable.

Article 63. This Law and its terms shall apply to research involving humans in all areas of knowledge, where applicable, and in accordance with the regulation.

Sole paragraph. The regulation shall provide for any specificities of research in the human and social sciences, with a view to the progress of science and the due application of this Law.

Article 64. With a view to the public good, the advancement of science at a national level and compliance with the principle of efficiency in public administration, the public or private bodies and entities responsible for analyzing and approving research in Brazil must continually improve their activities and services, in order to reduce the timeframes for their analyses and opinions.

Article 65. This Law shall come into force 90 (ninety) days after its official publication.

Brasília, 28 May 2024; 203rd year of Independence and 136th year of the Republic.

LUIZ INÁCIO LULA DA SILVA

Camilo Sobreira de Santana

Sonia Bone de Sousa Silva Santos

Nísia Verônica Trindade Lima