National Ethics Committee for Research

Questions & Answers

Version 1.1 of 19/02/2026

Introduction

The National Ethics Committee for Research – Inaep, a collegiate body, exercising the powers provided for in Article 2, item XXVI, of **Law No. 14,874, of May 28, 2024, and in Article 10 of Decree No. 12,651, of October 7, 2025,** This document provides the following clarifications regarding the implementation of the National System of Ethics in Research with Human Beings (Sinep). Inaep is responsible for regulating, overseeing, and ethically controlling research, aiming to protect the integrity and dignity of participants. These clarifications seek to safeguard legal security, uniformity of procedures, and the continuity of public service provision during the transition period.

What is the purpose of this document and who is it intended for?

This document is part of the process for implementing the legal and transitional measures in place until the publication of specific regulations by the National Ethics Committee for Research (INAEP). Its purpose is to clarify any doubts regarding the applicability of the legal provisions by the Ethics Review Bodies (CEPs), researchers, sponsors, and other stakeholders involved.

Therefore, until the publication of supplementary regulations, it is recommended that the transitional guidelines presented here be observed, with the aim of ensuring the protection and safety of research participants, as well as uniformity of understanding within the National Research Ethics System – Sinep.

This document compiles questions received within the scope of the Inaep Coordination's activities and presents guiding answers of a transitional nature, structured in a question-and-answer format, without prejudice to current legal and regulatory provisions.

UNIQUE ANALYSIS

Question	Response
What are the expectations for the implementation of the single analysis?	Law No. 14,874/2024 establishes that the ethical analysis of multicenter research (a protocol executed in more than one center) will be carried out by a single Ethics Committee (CEP), preferably that of the coordinating center, which will issue the opinion and notify the CEPs of the other participating centers (art. 14, §7). The implementation of a single analysis, centralized in the coordinating CEP, optimizes the ethical workflow and confers greater efficiency to the process of evaluating multicenter research. The expectation is for progressive implementation: the guideline is defined by law and foreseen in Decree No. 12,651/2025, while operational procedures (system flows, notification routines, and other adjustments) are still being consolidated by Inaep. This does not prevent the application of the legal guideline, but it may influence practical uniformity while the flows are standardized.
How does single analysis work and what changes in practice?	Multicenter research, conducted in different study centers by more than one researcher and following a single protocol, will now have: • Ethical analysis can be performed by a single Ethics Committee, preferably the one linked to the coordinating research center. A single ethical opinion, issued by the • Ethics Committee of the coordinating center, is valid for all participating centers. • The Ethics Committee that issues the single opinion must notify its decision to the other Ethics Committees of the participating centers. • Notifying the other postal codes eliminates the need to issue a new opinion for the same protocol. To avoid duplication of processes, it is recommended that institutions and Ethics Committees: • Organize your internal workflows to avoid duplicate submissions and parallel procedures;

Question	Response
	• Ensure that the opinion issued by the coordinating Ethics Committee is communicated to and filed by the other participating centers; Establish communication channels • between the Ethics Committees; Guide researchers on the • standardization of documentation. ***Important: a single analysis does not eliminate local responsibilities. Participating centers remain responsible for ensuring adequate conditions for conducting the study, including verifying technical and physical infrastructure, organizing logistics and recruitment compatible with the local context, as well as maintaining ongoing institutional responsibility for the protection, integrity, and well-being of participants under their supervision.***
With the single analysis, is it still necessary to process specific documents from each institution (e.g., infrastructure, recruitment)?	Yes, but it's essential to distinguish: • Ethical opinion: it is unique, issued by a single Ethics Committee (preferably that of the coordinating center), and is valid for all participating centers; and Local institutional authorizations: which remain the responsibility of • each center (not Ethics Committees), such as, for example, approval for the use of facilities. Thus, if there is a favorable ethical opinion from the responsible Ethics Committee (CEP), no additional opinion from a local CEP is required to "validate" the start of activities in centers already included in the approved protocol. It is up to the participating centers, for example, to verify the scope of the opinion, and whether the center and the activities carried out at that location are included in the protocol.
What contact information should be included? Should this information be included in informed consent forms in multicenter studies?	The opinion on multicenter studies should be issued by a single Ethics Committee, but this does not eliminate the need for the participant to have local channels of contact at the center where they are being treated. Participating centers retain local institutional responsibility and are the immediate point of reference for research participants. While there is no detailed operational standard from INAPEP (National Institute for Research and Educational Studies and Research), it is recommended to comply with the legal guideline without reducing participant accessibility. Therefore, the Informed Consent Form (ICF) must state, at a minimum: • Contact information for the Ethics Committee of the coordinating center (responsible for the ethical review of the protocol);

Question	Response
	• Contact information for the local research center and/or institutional channel of the participating • center; Contact information for the person(s) responsible for the research at the participating center.

PROTOCOL PROCESSING HIGH RISK

Question	Response
How will risk classification and the processing of high-risk protocols be handled during the transition?	Until the publication of specific regulations for risk classification within the scope of Sinep, protocols classified in special thematic areas remain considered "high risk," according to the criteria established in CNS/MS Resolution No. 466, of December 12, 2012, and in Conep/CNS/MS Circular Letter No. 172, of April 20, 2017. In accordance with Technical Note No. 1/2026-DECIT/SCTIE/MS, protocols that were being processed under the previous structure and had not yet been analyzed were redistributed to the Accredited Ethics Committees (CEPs) in a coordinated and gradual manner, to ensure legal certainty and the continuity of ethical analysis under the new legal competencies.
Is there a plan to regulate risk classification?	The Temporary Working Group (GTT), responsible for organizing the transition from the CEP/Conep System to Sinep, listed a set of essential normative acts that require regulation by Inaep. Within this set, the definition of risk classification criteria was identified as a preventive and strategic priority, to provide clarity on which protocols should be submitted to Accredited CEPs.
How will the transition of protocols (initial and amended) that were at CONEP and have been transferred to the Accredited Ethics Committees take place?	The initial protocols that were awaiting analysis were electronically redistributed to the Accredited Ethics Committees. Once an Accredited Ethics Committee takes over the analysis of the initial protocol, it becomes the reference instance for that project. Consequently, all amendments and notifications related to this protocol must be processed exclusively within the same accredited Ethics Committee, ensuring the continuity and history of the analysis.

Question	Response
What criteria are used to forward a protocol to an Accredited Ethics Committee?	During the transition, the criteria prioritize: • Operational capacity of the accredited CEP to absorb the demand. • Thematic affinity of the Ethics Committee in relation to the research topic (e.g., oncology, genetics), when applicable. • Balancing the system to minimize overload in specific centers and promote compliance with legal deadlines.
Can an accredited research ethics committee refuse to accept a new research protocol?	The Accredited Ethics Committee (CEP) is an essential body within the National System for Research Ethics (SINEP), competent to analyze high-risk protocols and also able to analyze low- and moderate-risk research. The redistribution of protocols carried out by Inaep has a legal basis. In situations of technical limitations or occasional operational overloads, the CEP relies on the institutional partnership of Sinep to ensure the proper processing of cases. We maintain permanently open communication strategies so that any occurrences are immediately reported to the Instance, enabling shared management of the workflow and preserving the speed and technical quality of the analyses.

ACCREDITATION

Question	Response
How will the accreditation strategy for new Ethics Committees be structured?	The accreditation process for new Ethics Committees (CEPs) is part of the action plan for evaluation and deliberation by INAPEP. Initially, although the process has not yet been submitted to the INAP Board for consideration, we foresee the following needs: • Formulation of regulatory guidelines (even if on an experimental or transitional basis) that define minimum criteria for accreditation;

Question	Response
	• That the Ethics Committees seeking accreditation have the physical infrastructure and technical qualifications of their members to meet the requirements of Law 14.874/2024 and Decree No. 12.651/2025. • That the institution as a whole provides the operational conditions and support to its CEP (Ethics Committee). • Progressive and strategic expansion of the number of accredited committees, in line with the complexity of the analyses and the institutional conditions necessary for the proper exercise of the powers provided for in Decree No. 12,651/2025. • Creating key performance indicators (KPIs) and deadlines for periodic reassessment, ensuring that decentralization does not result in a loss of ethical rigor.
How is it going? Communication with postal codes?	Institutional communication with the Ethics Committees has been treated as a strategic axis of the transition, conducted in a continuous, transparent, and guiding manner. Key initiatives include: • Guidance notes such as Technical Note No. 43/2025- DECIT/SECTICS/MS and Technical Note No. 1/2026-DECIT/SCTIE/MS, disseminated to Ethics Committees throughout the country. • Active listening initiatives, such as the "Participatory Contribution Form for the Development of the New Research Platform with Human Beings" . • Alignment and capacity-building initiatives, including a meeting of accredited Ethics Committees (Nov/2025), a webinar (Jan/2026), and meetings with coordinators of accredited Ethics Committees, with support from the Ministry of Health. Additionally, the Department of Science and Technology, of the Secretariat of Science, Technology and Innovation in Health of the Ministry of Health (Decit/SCTIE/MS), in support of Inaep, has incorporated into its action plan the continuous evaluation of governance models, training and support for Ethics Committees, in alignment with best practices and with the guidelines established by the new legal framework.

POST-STUDY ACCESS

Question	Response
Is post-study access (provision) optional? How does the rule work?	The continuity of treatment after the study is not an expectation, but a legal obligation, applicable from the research planning stage to the post-study period. In light of Article 31 of Decree No. 12,651/2025 and Articles 30 to 36 of Law No. 14,874/2024, the post-study access (or provision) program is not resolved by mere notification, and its submission to the prior ethical review of the competent Ethics Committee (CEP), generally the CEP coordinating the study, is mandatory. At the end of the trial, migration to the post-study program is treated as automatic when there is clinical benefit and the foreseen conditions are met, including: ● The medication is the best available therapeutic alternative; the risk-benefit ratio is ● favorable; severity of the clinical condition and ● unmet medical need. The decision is based on an individualized assessment (researcher, sponsor, and participant), preserving the autonomy of the Ethics Committee to request additional information and monitor the process, always guided by the well-being of the participant.
Does the post-study access program need to be submitted for approval, or is notification sufficient? When to submit So what should I present?	It must be submitted for evaluation by the competent Ethics Committee. Notification alone is not sufficient. Article 31, §1 of Decree No. 12.651/2025 stipulates that the program must be developed by the sponsor and submitted for ethical review. Regarding the timing: ● The post-study access plan must be submitted before the start of the clinical trial (Article 30 of Law No. 14,874/2024); The post-study supply program must be ● submitted to the Ethics Committee when, at the end of the trial (or individual participation), the need for continued experimental treatment is characterized, based on individual assessment.

Questions	Response
	The submission must occur in a timely manner to: ● Allow for prior ethical review; Ensure ● automatic migration of the participant to the post-study access program; Avoid therapeutic discontinuation. ● Until specific regulations are issued by Inaep, it is recommended that the submission contain, at a minimum: ● Program description; Technical ● justification and risk-benefit ratio; Justification for the ● need for continued treatment, based on individual risk-benefit assessment; Clinical and ethical criteria for inclusion and maintenance of ● participants; Participant safety monitoring plan; Expected duration of provision and termination ● conditions, in light of Article 33 of Law No. 14,874/2024; Responsibilities of ● the sponsor, researcher, and institution; Care transition strategies, when applicable; Indication of the need for sanitary authorization ● by the National Health Surveillance Agency (Anvisa), when pertinent. ● ● ● Other additional information that may be relevant to the process.

CONSIDERATIONS OF THE FUNCTIONAL STRESSES AND THE STRESSES

TRANSITIONAL GUIDELINES

The institutional transition from the CEP/Conep System to Sinep demands action guided by legal certainty and strict adherence to current legislation. The guidelines proposed here are fundamental to the governance of ethics in research, aiming to harmonize norms and provide predictability to the sector during this period of change.

This transition process is intended to establish a solid technical basis for future regulatory decisions, strengthening participant protection and mitigating operational asymmetries. Institutionally, the priority is clarity of roles and decisional stability in consolidating the National Authority.

Inaep will adopt the proposed measures gradually and in a coordinated manner, prioritizing the modernization of processes and transparency. Finally, it is reiterated that strengthening this regulatory environment is essential to promote research with human subjects in Brazil, aligning scientific and technological development with the centrality of the rights of research participants.

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What changed in this version (1.1, dated 02/19/2026):

1. Textual Duplication

On page [1], in the question “What is the purpose of this document and who is it intended for?” , identified himself

Duplication of a section, resulting from a material editing error. It is clarified that the correct content...

This corresponds to only one occurrence of the aforementioned passage, without any technical detriment to the document.

2. Correction of normative reference

On page [6], in the question “How is communication with the postal codes going?” , In the first point:

where it reads:

Technical Note No. 01/2025-GTT

Read as:

Technical Note No. 43/2025-DECIT/SECTICS/MS.

National Ethics Committee for Research (Inaep)

Provisional guidelines: questions and answers

Version: 1.1, dated 02/19/2026