Ministry of Health
Secretariat of Science, Technology and Innovation in Health
Department of Science and Technology

TECHNICAL NOTE No. 1/2026-DECIT/SCTIE/MS

1. SUBJECT

1.1. Guidelines regarding the processing of research protocols involving human subjects, the definition of competencies within the National System of Ethics in Research with Human Subjects, the ethical analysis of protocols with the Ministry of Health as the proposing institution, the exceptional extension of the accreditation of Research Ethics Committees, and the procedures applicable to biobanks, in the context of the implementation of the National Ethics Body for Research.

2. CONTEXTUALIZATION 2.1.

With a view to legal certainty, ethical and regulatory compliance, and the continuity of public service provision, pursuant to Law No. 14,874 of May 28, 2024, Decree No. 12,651 of October 7, 2025, and SECTICS/MS Ordinance No. 85 of October 14, 2025, the Department of Science and Technology of the Secretariat of Science, Technology and Innovation in Health of the Ministry of Health (Decit/SCTIE/MS), after approval of the rationale and guidelines by the members and in its capacity as coordinator of the Temporary Working Group (GTT) responsible for assisting in guidance on operational decisions and contributing to the continuity of ethical evaluations during the transition phase to the National Ethics Committee for Research (Inaep), resolves, through this Technical Note No. 1/2026-DECIT/SCTIE/MS, to provide guidance and clarifications:

I - **Processing of high-risk protocols** within the scope of the National Research Ethics System; **Low and moderate-risk research protocols** where II -

the proposing institution on the Brazil Platform is the Ministry of Health; III - **Validity of the accreditation registration** of Research Ethics Committees (CEPs); IV - **Development and accreditation of Biobanks,** to resolve procedural doubts arising in the transition process.

This guidance responds to requests submitted by Ethics Committees, researchers, and sponsors to the Working Group on Clinical Research (GTT), aiming to improve the operational efficiency of the system. It is important to note that this document addresses procedural gaps not fully covered by the existing legislation, but which are essential for the gradual and safe advancement of innovations foreseen in the new legal framework for clinical research in Brazil.

2.3. Considering the imperative of maintaining the gradual progress in implementing the innovations foreseen in Law No. 14,874/2024 and Decree No. 12,651/2025, for the proper functioning of the National System of Ethics in Research with Human Beings, this Technical Note aims to provide guidance regarding doubts raised by Research Ethics Committees, researchers, and sponsors since the beginning of the process.

This Technical Note addresses the role of the Temporary Working Group, as well as clarifying complementary issues to make the ethical processing of research protocols and the functioning of the Committees more efficient. It particularly emphasizes the importance of safeguarding the authority and legitimacy of the Ethics Committees' operations during the transition period, reaffirming their legal role as ethical review bodies. This Technical Note also addresses transitional aspects not covered in Law No. 14.874/2024 or Decree No. 12.651/2025, but which have become necessary in the context of the transition process.

2.4.

3. INITIAL PROCESSING OF RISK RESEARCH PROTOCOLS HIGH

In addition to the guidelines provided on the process of section 3.1, processing of high-risk research protocols described in Technical Note No. 43/2025-Decit/SECTICS/MS[1] additional procedures should be adopted to ensure the proper processing of high-risk research protocols. 3.2.

Considering that only accredited Ethics Committees (CEPs) are recognized as the ethical review body for high-risk research protocols, and that the Plataforma Brasil platform currently lacks the necessary resources to automatically direct all high-risk research protocols to accredited CEPs as soon as they are submitted for ethical review, it is necessary that every accredited CEP, upon receiving a high-risk research protocol (HR) for initial processing, in its capacity as the CEP of the Coordinating Center of the study, follow the instructions below to ensure expedited processing in accordance with current regulations: a) As the CEP of the Coordinating Center, upon receiving a research protocol for initial processing that is marked as belonging to one or more thematic areas, as defined in item IX.4 of CNS Resolution No. 466/2012, the accredited CEP must verify whether the protocol in question

actually falls within the thematic area(s) indicated at the time of submission to Plataforma Brasil.

When the accredited Ethics Committee (CEP) determines that the research protocol does not fit within the thematic area (high risk), the protocol must be returned to the researcher requesting the correction of the registered information, and upon its return, the CEP must proceed with the ethical analysis.

b) If the accredited Ethics Committee concludes that the research protocol does, in fact, fall within one or more thematic areas indicated by the researcher, characterizing it as high-risk research, an administrative referral procedure must be adopted, exclusively for the purpose of directing the protocol to the competent body. In this case, the protocol will be processed without ethical analysis and without a deliberative character, with the issuance of a substantiated opinion classified as 'Approved', exclusively to enable the transfer of the protocol, via Plataforma Brasil, to INAEP, responsible for promoting its distribution to an accredited Ethics Committee.

It is clarified that this procedure does not constitute a statement of ethical merit on the part of the accredited Ethics Committee, nor does it authorize the commencement of research, its sole purpose being to ensure the speed and correct allocation of the protocol to the legally competent body for ethical analysis. The Ethics Committee coordinator himself may carry out all stages of the process, and must include the message "In compliance with the requirements of the Ethics Committee" in all mandatory fields of the report.

In accordance with Technical Note No. 1/2026-DECIT/SCTIE/MS and to comply with Article 9, § 1, item II, of Law No. 14,874, of May 24, 2024, and Article 25, item II, of Decree No. 12,651, of October 7, 2025, it is hereby informed that this "Approved" opinion does not represent the opinion of the Ethics Committee (CEP) regarding the ethicality of the research protocol and that the release of this opinion has the sole purpose of accelerating its transfer process for processing in an accredited Ethics Committee (CEP). As the competent and legitimately designated body for the ethical analysis of projects classified as high-risk, the accredited Ethics Committee (CEP) is effectively responsible for the ethical review of the research protocol and the issuance of the substantiated opinion.

These procedures described must be adopted by all accredited CEP 3.3.

4. PROCESSING OF RESEARCH PROTOCOLS AT THE MINISTRY OF HEALTH

4.1. In order to comply with the established regulatory deadlines for the ethical processing of research protocols and to avoid harming the development of scientific research that complies with national ethical guidelines, it is recognized that it is necessary to transfer to the correct ethical review body the set of research protocols submitted for ethical review that have the Ministry of Health registered as the proposing institution on the Brazil Platform.

4.2. According to the established procedural flow prior to the publication of Law No. 14,874/2024 and Decree No. 12,651/2025, the ethical review body responsible for analyzing research protocols in which the Ministry of Health was the proposing institution was the National Research Ethics Committee (Conep). However, according to Article 40 of Decree No. 12,651/2025, Conep is currently responsible for appeals. Therefore, it is determined that, until further notice from Inaep on this matter, the ethical review of low- and moderate-risk research protocols will be the responsibility of the accredited Research Ethics Committees (CEPs) of institutions linked to the Ministry of Health (e.g., foundations, institutes, hospitals, etc.), and the ethical review of high-risk research protocols with the Ministry of Health as the proposing institution will be the responsibility of the accredited CEPs.

4.3. Both research protocols that are in the initial processing stage (PO), as well as amendments and notifications of protocols that have been previously analyzed and approved by Conep, will be addressed.

5. EXTENSION OF ZIP CODE ACCREDITATION REGISTRIES

In order to prevent situations of legal and institutional uncertainty and to ensure the regular, legitimate and uninterrupted continuity of the functioning of Research Ethics Committees (RECs), the automatic extension, for 1 (one) year, of the accreditation of RECs whose term of validity ended in the year 2025 is established, on an exceptional basis, counted from the respective expiration date.

5.2. The exceptional extension mentioned in the previous item does not eliminate or replace the obligation of the institution maintaining the CEP (Ethics Committee) to promptly submit the documentation necessary for the analysis and renewal of accreditation, in accordance with the terms and deadlines stipulated in Article 8 of CNS Resolution No. 706, of February 16, 2023. Compliance with any requests for supplementary or corrective documentation made during the course of the procedural instruction remains equally mandatory.

5.3. The accreditation renewal processes will remain in regular administrative processing and, once the respective technical analysis is completed, will be submitted, in due course, to Inaep for deliberation, producing full administrative effects from the date of the collegiate decision.

6. PROCESSING OF DEVELOPMENT PROTOCOLS BIOBANKS

6.1. Regarding biobank development protocols, a regulatory gap was identified concerning the clear and unequivocal definition of the competent bodies and applicable procedural flows, especially in the context of the transition to INAPEP. Therefore, guided by the principles of legal certainty and the protection of participants, the processing of procedures related to biobank development protocols is hereby temporarily suspended, regardless of their registration status, until INAPEP issues a specific statement.

6.2. The suspension mentioned in the previous item does not apply to biobanks already approved by the CEP/Conep System that are in good standing.
For these, the following rules apply:

6.2.1 Operational Continuity: They may maintain their activities, provided they are restricted to the conditions, purposes, and procedures expressly approved in their original registration.

6.2.2 Prohibition of Changes: During the transition period, any changes to regulations, governance, or operational routines that have not been previously approved by the competent authority are prohibited.

6.2.3 Institutional Responsibility: The sponsoring institutions must strengthen internal control measures to ensure ethical compliance, traceability, and the preservation of participants' rights.

Inaep The exceptional situation now established will be indicated as the subject of priority reassessment by (National Institute for Research and Graduate Studies), and supplementary guidelines will be released regarding the resumption of procedures, the definition of competencies, and the procedures applicable to biobank development protocols.

7. FINAL CONSIDERATIONS

7.1. The implementation process of the National System of Ethics in Research with Human Beings and the National Instance of Ethics in Research – Inaep, as stipulated in SECTICS/MS Ordinance No. 85, of October 14, 2025, is underway and is being conducted in a planned, coordinated, and gradual manner within the Ministry of Health. In this context, the present transition has as its central guideline to ensure the continuity of the ethical analysis of research protocols with human beings, preserving the regularity of the flows, the legitimacy of the decisions, and the full functioning of the Research Ethics Committees.

The guidelines compiled in this Technical Note and in other administrative acts of the Temporary Working Group (GTT) aim to offer the scientific community, researchers, and Research Ethics Committees clear and up-to-date references for conducting ethical processes during the transition period. The objective is to reduce uncertainties, promote predictability, and enable necessary operational adjustments, while maintaining alignment with current regulations and protecting research participants.

This Technical Note therefore constitutes a tool to support decision-making and the proper conduct of research activities, without prejudice to future updates resulting from guidelines from the National Ethics Committee for Research or the issuance of new regulations. Finally, the institutional commitment to transparency and ongoing dialogue with the [National Ethics Committee] is reaffirmed.

The scientific community and the gradual consolidation of a more efficient, secure National System of Ethics in Research with Human Beings, aligned with best ethical practices.

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REFERENCES

[1] See Annex I for frequently asked questions about Technical Note No. 43/2025-Decit/SECTICS/MS

ANNEX I - FREQUENTLY ASKED QUESTIONS RELATED TO TECHNICAL NOTE NO. 43/2025-DECIT/SECTICS/MS.

Why was the research protocol that was under review at CONEP forwarded to a different CEP (Ethics Committee) than that of the proposing institution?

If the research protocol was being processed by CONEP and was transferred to a different CEP than the one that performed the initial analysis, this occurred because the project qualified as high-risk research, that is, registered as a thematic area under the terms of CNS Resolution No. 466/2012.

As described in Technical Note No. 43/2025-Decit/SECTICS/MS, any research protocol that falls within one or more of the thematic areas defined by CNS Resolution No. 466/2012 will be considered high-risk. Therefore, in accordance with Law No. 14.874/2025 and Decree No. 12.651/2025, the protocol must be analyzed by an accredited Ethics Committee (CEP), the competent and legitimately designated body for the ethical analysis of projects classified as high-risk.

It should also be noted that all procedures, including any amendments and notifications, will also be handled by the accredited Ethics Committee (CEP), without the need for analysis by a certified Ethics Committee (CEP).

Are there any additional procedures that the researcher must follow to regularize the processing and ensure the continuity of the ethical review of the research protocol?

After the transfer is completed, the researcher must be aware of possible document rejections or pending issues raised by the accredited Ethics Committee (CEP). As the competent and legitimately designated body for the ethical analysis of protocols classified as high-risk, the accredited CEP has the authority to request updates or supplementary documents to complete the research protocol, as well as to decide on its approval.

What are the next steps that the researcher and the Ethics Committee of the proposing institution should expect after the transfer?

Once the transfer is completed, the researcher and the Ethics Committee of the proposing institution must await the decision of the accredited Ethics Committee, which may result in rejection.

Documentary or opinion issuance. It should be noted that, in cases where it is identified that the research protocol was incorrectly registered as belonging to a thematic area by the researcher, an opinion will be issued, as a mere formality, without ethical analysis, by the accredited Ethics Committee (CEP), containing the information that the ethical analysis body for that research protocol is the accredited Ethics Committee of the proponent's institution. In these cases, the project's affiliation will be changed again, and the initial approval opinion issued by the accredited "origin" Ethics Committee will remain valid.

How will the Ethics Committee (CEP) of the proposing institution monitor the research protocol that has been submitted to an accredited Ethics Committee?

Once the research protocol has been transferred to an accredited Ethics Committee (CEP), the processing then takes place exclusively within that accredited CEP. The CEP of the proposing institution has the right to request information and clarifications from the accredited CEP or from INAPEP itself, in order to stay updated on the processing of a protocol that was initially under its responsibility.

Is it mandatory to continue sending research reports to the Ethics Committee?

The submission of research reports is a requirement established in item IX of article 27 of Law No. 14.874/2024. Therefore, they must be submitted whenever requested by the Ethics Committee, or at least once a year during the research period.

This document was electronically signed by **Meiruze Sousa Freitas, Director of the Department of Science and Technology,** on January 12, 2026, at 7:16 PM, Brasília time, pursuant to § 3, art. 4, of Decree No. 10,543, of November 13, 2020; and art. 8, of Ordinance No. 900 of March 31 , 2017.

This document was electronically signed by **Ana Lúcia Silva Marçal Paduello, Coordinator of the National Research Ethics Committee,** on January 13, 2026, at 11:57 AM, Brasília time, pursuant to § 3, of Article 4, of Decree No. 10,543, of November 13, 2020; and article 8 of Ordinance No. 900 of March 31, 2017.

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