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Metrics of a Research Ethics Committee: efficiency and effectiveness

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Abstract

This cross-sectional study with a quantitative approach, which used secondary data from Plataforma Brasil, aimed to analyze the performance indicators of the Research Ethics Committee of the General Hospital of Fortaleza between 2018 and 2024, focusing on the efficiency and effectiveness of the ethical review process. Significant variations were identified in the average times of the analyzed stages, especially in the initial phases, such as document validation and responses to pending issues. In contrast, stages related to the work of the reviewers showed greater stability and predictability. Statistical analyses confirmed relevant differences among the stages, highlighting critical points that require adjustments in workflows and improvements in management. Continuous monitoring through indicators strengthens ethical governance, guides the improvement of the evaluation system, and contributes to enhancing institutional practices, thereby strengthening research ethics in the country.

Keywords: Ethics committees, research. Indicators of health services. Efficacy. Efficiency. Health evaluation.

Resumo

Métricas de um Comitê de Ética em Pesquisa: eficiência e eficácia

Este estudo transversal com abordagem quantitativa, que utilizou dados secundários da Plataforma Brasil, teve o objetivo de analisar os indicadores de desempenho do Comitê de Ética em Pesquisa do Hospital Geral de Fortaleza entre 2018 e 2024 relativos a eficiência e eficácia do processo de avaliação ética. Identificaram-se variações significativas nos tempos médios das etapas analisadas, especialmente nas fases iniciais, como validação documental e resposta a pendências. Em contrapartida, as etapas relacionadas à atuação dos relatores demonstraram maior estabilidade e previsibilidade. Análises estatísticas confirmaram diferenças relevantes entre as etapas, que evidenciam pontos críticos que requerem ajustes nos fluxos e melhorias na gestão. O monitoramento contínuo por meio de indicadores reforça a governança ética, orienta o aperfeiçoamento do sistema de avaliação e contribui para a qualificação das práticas institucionais, fortalecendo a ética em pesquisa no país.

Palavras-chave: Comitês de Ética em Pesquisa. Indicadores de serviços. Eficácia. Eficiência. Avaliação em saúde.

Resumen

Métricas de un Comité de Ética en Investigación: eficiencia y eficacia

Este estudio transversal con enfoque cuantitativo, que utilizó datos secundarios de la Plataforma Brasil, tuvo como objetivo analizar los indicadores de desempeño del Comité de Ética en Investigación del Hospital General de Fortaleza entre 2018 y 2024, en relación con la eficiencia y la eficacia del proceso de evaluación ética. Se identificaron variaciones significativas en los tiempos promedio de las etapas analizadas, especialmente en las fases iniciales, como la validación documental y la respuesta a observaciones. En cambio, las etapas relacionadas con la actuación de los relatores mostraron mayor estabilidad y previsibilidad. Los análisis estadísticos confirmaron diferencias relevantes entre las etapas, evidenciando puntos críticos que requieren ajustes en los flujos y mejoras en la gestión. El monitoreo continuo mediante indicadores refuerza la gobernanza ética, orienta el perfeccionamiento del sistema de evaluación y contribuye a la cualificación de las prácticas institucionales, fortaleciendo la ética en investigación en el país.

Palabras clave: Comités de ética en investigación. Indicadores de servicios. Eficacia. Eficiencia. Evaluación en salud.

The authors declare no conflict of interest.
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Research

All research involving human beings must comply with strict ethical standards, as established by the National Health Council (CNS) Resolution 466/2012 [1], which lists several points, including assessing participants, obtaining informed consent, focusing on risks and benefits, protecting the rights of those involved, having qualified researchers, and monitoring research phases. Thus, it is necessary to focus on ethical values such as transparency, respect, honesty, good governance, and seriousness in scientific research based on co-responsibility, collaboration, and mutual trust [2].

Recent years have seen the consolidation of the discussion on open science, which advocates the democratization of access to scientific knowledge as an essential premise for equitable and sustainable development. This discussion directly impacts the role and practice of research ethics committees (REC), as it demands higher transparency, data sharing, and accessibility in ethical review processes. It is necessary to consolidate a national open science policy, focused on best practices for scientific review and governance, which represents a challenge and, at the same time, an opportunity for RECs to adapt to the new demands of the contemporary scientific landscape [3].

Recently enacted, Law 14,874/2024 [4] established the National Research Ethics System, which regulates bioethics in the course of studies. The law text is clear in determining that RECs must review research documentation within ten business days after submission, subsequently accepting or denying, in addition to issuing the opinion within 30 business days. In turn, researchers have ten business days, extendable for an equal period, to address any pending issues. The collegiate body's decisions can be appealed at the local level and, ultimately, at the national level [5].

Continually protecting participants in the face of so many inherent challenges and risks requires reflection on the dynamic context of bioresearch. The maxim that it is always necessary to debureaucratize, when effected at the expense of participant safety, promotes deleterious effects that oppose what it recommends [6].

The pursuit of higher effectiveness and standardization in ethical review is not exclusive to Brazil. In Latin America and the Caribbean, a study coordinated by the Pan American Health Organization (PAHO) [7] found that less than a third of countries have diligent institutional policies for the qualification of REC members and the consolidation of national research ethics systems. This situation shows regional disparities and reinforces the urgent need for initiatives that promote strong ethical governance.

The careful review of processes, especially in organizational and institutional contexts, clearly requires the application of the concepts of efficiency and effectiveness, as, although frequently used in common sense, they acquire distinct yet complementary meanings for public management and administration. Despite the importance of patient safety indicators, few studies have quantitatively analyzed their performance indicators in the Brazilian context, especially in large hospitals.

Efficiency is directly related to rational and optimized use of available resources, in order to achieve expected results with the lowest possible cost from financial, human, or temporal perspectives. According to Maximiano, *efficiency is doing things well and correctly* [8], referring to the competence of implementing processes with quality, prioritizing economy and productivity, avoiding waste. In turn, as noted by Frasson, effectiveness concerns the capacity *demonstrated by the project of achieving previously established objectives and goals* [9], with a focus on the final results obtained, without rigidly considering how resources were employed. Thus, while efficiency highlights the means, effectiveness focuses on the ends, with both being indispensable in performance review for institutions, projects, and programs.

These two concepts, when applied to REC processes, are notable due to the need to ensure, in addition to participant safety and integrity, that administrative and regulatory procedures are conducted in a timely manner. Ethical governance and technical capacity, combined with quality and speed, should be the foundation of REC operation. The delay in issuing opinions can compromise the execution of scientific projects, delay relevant results, impact funding, and hinder therapeutic innovations [10].

The Hospital Geral de Fortaleza (HGF) REC, operating since 1998, holds bi-weekly meetings in its own seat, located in Fortaleza/CE. Its composition

is established by Internal Ordinance 028/2025 [11], consisting of a coordinator, an assistant coordinator, six regular members, three alternates, and a secretary. The renewal of its accreditation was effective on March 7, 2024, according to Official Letter 183/2024, issued by the National Commission for Research Ethics (CONEP) [12].

Given this institutional arrangement and the importance of quality in research ethics review processes, there arose the following guiding question: how do HGF/REC performance indicators reflect its work process, considering efficiency and effectiveness?

The study has the proposal of contributing toward enhancing the institutional scientific integrity policy by boosting the quality of the methods and the effectiveness of the mission of each REC in Brazil. Considering the legal requirements and everyday challenges of researchers and research institutions, there is urgent need for studying and reviewing the operation of these institutions in improving services provided to the academic community and society and the extent to which the indicators show compliance with current legislation.

This context underscores the relevance of this study, which proposes a consideration of how the committee has operated over the years. Beyond addressing numbers, the point is understanding the internal structure, seeing potential, tracing challenges, and, mainly, providing means so the ethical review process improves in clarity, quality, and responsibility, especially when it comes to research involving human beings.

Method

This is a cross-sectional study with a quantitative approach, which used secondary data. This type of study is defined by collecting information at a given time, or over a relatively short period of time, which provides a clear observation of how a certain condition or characteristic is present in a specific group. In this approach, researchers merely follow data as they are presented, without interfering with or modifying the factors involved, meaning there is no experimental manipulation, only observation of existing relationships [13].

Performance reports produced by the Plataforma Brasil (PB) were collected between 2018 and 2024, a period during which the data were fully available. The information used was collected by researchers, formally authorized by the HGF general management.

From these reports, the raw number of projects, amendments, and notifications was extracted, and a historical series was created with measures of central tendency and dispersion of execution, taking into account the following variables:

- document validation (average time between the date of submission to the REC and the end of the document check: project acceptance or outstanding issues raised);
- response to documentary pending issues (average time between the issuance of the documentary pending issues and the researcher's submission of the response to the REC/CONEP);
- preparation of rapporteur opinion (average time between the rapporteur's acceptance to perform the ethical review and the completion/issuance of rapporteur opinion);
- preparation of collegiate opinion (average time between the completion/issuance of rapporteur opinion and the completion/issuance of collegiate opinion);
- preparation of the consolidated opinion (average time between the conclusion/issuance of collegiate opinion and that of consolidated opinion);
- response to pending issues (average time between the issuance of a pending issue through the consolidated opinion and the submission by the researcher and the response to the REC/CONEP).

Data analysis used descriptive and inferential statistical techniques. Intragroup comparison used the analysis of variance (ANOVA) test for repeated measures, followed by Tukey's *post-hoc* test to identify significant differences between the analyzed variables. Statistical calculation and boxplot graph used the R software (version 4.4.1), and preparation of spreadsheet and bar graph used Microsoft Excel 365 software [14,15].

The use of ANOVA and *post-hoc* tests, such as Tukey's, enables not only checking for statistical differences between groups but also guiding

operational adjustments in institutional flows of ethics committees [16].

Ethical reviews must go beyond aspects related to informed consent and data confidentiality, encompassing a critical analysis of the statistical methods used. The inadequacy or misuse of statistical tests can compromise the validity of the results and conclusion, and consequently, the ethical integrity of the study. RECs are responsible for verifying the relevance and appropriateness of statistical analyses in submitted projects, that is, ensuring that chosen methods are suitable for study objectives and collected data, contributing toward research with methodological rigor and ethical responsibility [17].

The study was approved by the HGF/REC, respecting the determinations of CNS Resolution 466/2012 [1].

Results

Significant instabilities and transformations marked the ethical review process conducted by the HGF/REC in the analyzed period. Throughout these seven years, we observed non-linear trajectory, with significant variations in the number of projects submitted, the regularity of registrations, and processing times. This fluctuation shows, in addition to the complexity of the committee's internal functioning, the challenges as to its capacity to maintain stable and predictable performance due to external factors. Workflow efficiency and deliberative effectiveness seem to have been directly influenced by structural changes, emergency health contexts, and even some operational limitations.

Chart 1. Stages of the ethical review in numbers, 2018 to 2024

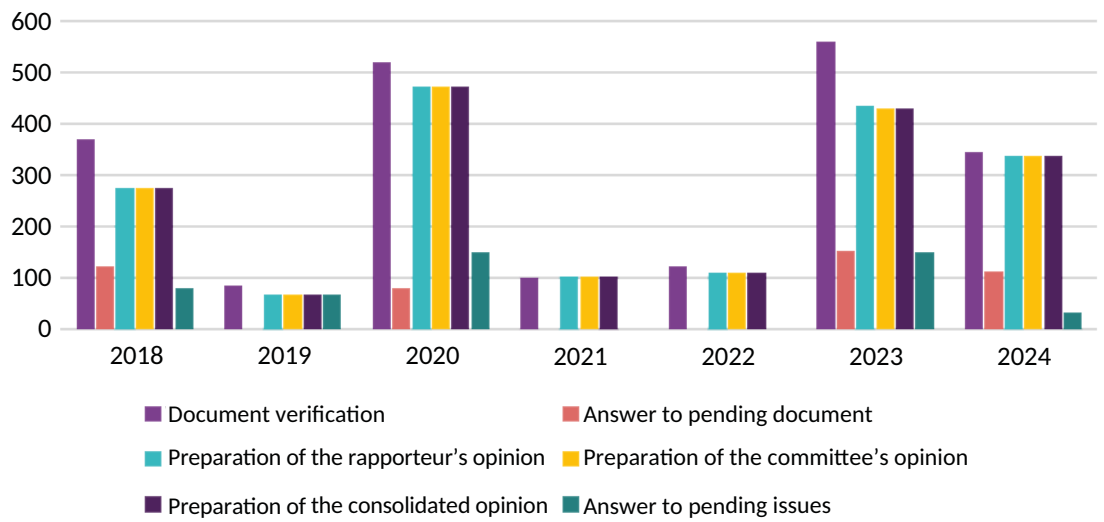


Chart 1 clearly illustrates the variation in the volume of activities recorded in the various stages of the ethical process during the analyzed period, which suggests flexibility and adaptability of the structure and reflects the constant improvement in the context of indicators. The document validation stage, for example, showed significant growth, from 84 records in 2019 to 557 in 2023. This notable increase, in addition reflecting greater demand for reviews, required the board to make an above-average effort, expanding its problem-solving capacity. In this period, we note the performance in 2020, with 517 validations, a year in which, even in the face of the COVID-19 pandemic, the continuity of analyses was ensured with technical dedication and collective effort, thanks to the strong institutional commitment of the members.

The data indicated challenges in efficiency, due to the increased response time during periods with higher backlog volume, as well as in effectiveness, due to the variation in the average time of the stages and the difficulty in following standardized procedures during the period of the

records. These aspects are further explored in Table 1, which summarizes the measures of central tendency and dispersion of the average times (in days) for each stage from submission to outcome.

Table 1. Measures of central tendency and dispersion (in days) of actions executed, 2018 to 2024

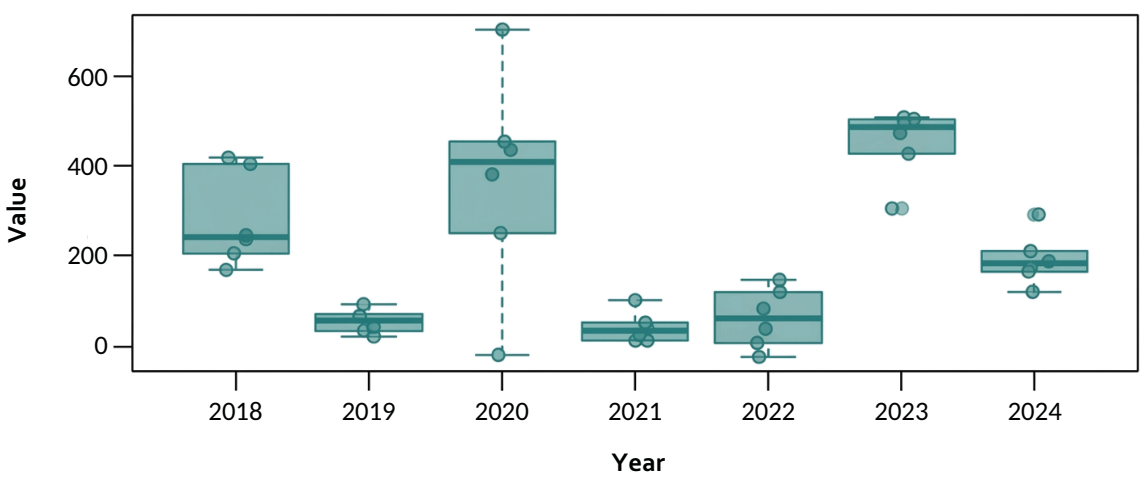
Action	Mean	Median	Standard deviation	Interquartile range
Document validation	5.00	3.30	15.10	6.00
Response to documentary backlog	7.13	10.10	6.96	12.80
Acceptance by rapporteur	1.13	1.00	0.61	0.80
Preparation of rapporteur's opinion	5.66	4.60	1.96	4.10
Preparation of collegiate opinion	2.41	2.20	0.68	1.00
Preparation of consolidated opinion	1.33	1.10	1.25	1.80
Response to backlog	7.14	9.20	7.08	13.70

Table 1 expands on the temporal performance of the flow, highlighting its agility and predictability in its various phases. Speed and efficiency are evident in stages such as the rapporteur's acceptance (average of 1.13 days) and the preparation of collegiate's opinion (average of 2.41 days), showing the capacity to maintain a work pace compatible with legal and institutional demands. The roles are well-defined among the members, and the internal processes are well-distributed, factors indicated by the visible standardization of deadlines now observed.

However, variability was observed in the document validation stage, with a standard deviation (SD) of 15.1 days and an interquartile range (IQR) of 6 days, indicating inconsistency in execution time. High dispersion (SD=7.08; IQR=13.7) was also observed in the response to backlog, suggesting instability in researcher behavior or operational delays.

Chart 2 reinforces this interpretation by representing the annual distribution of the number of processes reviewed. Operational control and greater predictability were shown by the progressive growth and stabilization in the period, particularly in 2023. In turn, 2020 is noted for its greater discrepancy, with wide dispersion and the presence of extreme outliers, reflecting an atypical context.

Chart 2. Annual distribution of the number of processes reviewed, 2018 to 2024



Research

Analysis of variance for repeated measures demonstrated statistically significant differences between the average times of the stages (p<0.05), confirming the heterogeneity of the internal processes. Tukey's *post-hoc* test indicated longer average times in the documentary validation and response to backlog stages, which may be related to technical diligence in the initial analysis of documents and the need for project adjustments to current ethical standards. These results reinforce the pedagogical role of the committee, which acts not only as a review body but also as a guide for good research practices; however, there is clear need for reviewing these points to ensure greater efficiency.

Although ANOVA provides a general, even superficial, view of the differences, the interpretation should not disregard contextual and operational factors that may have influenced the execution of processes over the years. While some phases occur quickly and consistently, others present longer execution times and mobility, indicating opportunities to improve operational efficiency and standardize processes.

Discussion

Analysis of HGF/REC performance indicators between 2018 and 2024 show the need for systematic monitoring of the entire ethical review process. Although the committee shows maturity, with some well-structured stages, deficiencies are observed in the initial stages, which compromises the efficiency of the flow.

Consistently with this situation, studies indicate the initial processing stage as one of the most prevalent bottlenecks in ethical review in Brazil. The heterogeneity in initial response time is associated with the lack of uniformity among RECs, as well as with the demanded overload and the high turnover of administrative teams. The lability in these factors and the extensive average times observed reinforce this trend [10].

In contrast, continuity can be observed in stages related to rapporteurs working as a collegiate body, which is a positive indicator, as it suggests consistent internal organization and technical skill. The differential of members with accumulated experience in bioethical reviews and continuous training is decisive for speed and quality in issuing opinions, and also in monitoring research [2].

With the enactment of Law 14,874/2024 [4], which regulates deadlines and directly holds committees responsible, especially if they intend to apply for accreditation seal at some point, meeting legal requirements, by aligning the average time of their actions, denotes satisfactory compliance with national guidelines. Beyond legal compliance, it is clearly advocated the need to constantly evaluate REC performance indicators, integrating aims toward improving the quality of services provided, from the viewpoint of professionals and public management [6].

Similarly, procedural compliance does not, in itself, ensure the ethical effectiveness of RECs. Authors argue that there is a global shortage of robust methods to measure the real impact of ethical review on participant protection and scientific integrity [18].

This law, which establishes guidelines for ethics in research with human beings, relaxes essential requirements for participant protection, since the discontinuation of CONEP, which will be replaced with an agency linked to the Ministry of Health, making processes vulnerable to external, political pressures and lobbies. Furthermore, social control is weakened, which compromises impartiality in the regulatory process, opening space for conflicts of interest and government interference [6].

The peak in the number of submitted research papers amid the pandemic context experienced in 2020, with a subsequent drop in the following year, may justify the fluctuation in the number of annual processes, considering the imposition of adversities in all sectors, especially in health care, requiring the workflow to be dynamically adapted. Interruptions, suspensions in committees, and difficulties adapting to remote work coincided with a significant increase in submissions, during a period when much was being studied about COVID-19 and its propositions [19,20].

Stages such as response to documentary backlog and response to backlog showed years with a total lack of records, such as 2019, 2021, and 2022. This result may have a negative aspect, indicating failures in data entry standardization; or a positive aspect, namely, low use of these steps, which may reflect improved quality of prior guidance to

researchers, reducing the need for rework and ensuring improved quality of submissions, suggesting advances in communication between the committee and proponents, and improvement in internal educational processes.

Despite annual variations, activities related to preparation of opinions (rapporteur, collegiate, and consolidated) showed consistent performance, indicating a high degree of technical-scientific maturity and organization. The safety and credibility of the review process were found to be in line with the members' adherence to the ethical and procedural principles that govern project review, reflecting the stability observed in these phases.

Some failures can compromise indicator reliability and underscore the need for high rigor in data entry for researcher submission and in documentary reception and review (inherent to the administrative team). The lack of compliance of some attached documents, such as informed consent form, schedule, cover sheet, and data collection instrument, was a frequent reason for ethical objection [21].

In this study, it was clear that a priority area of attention is the initial stages, with the greatest delays in average response time. The review process performance can be optimized with more streamlined systems and direct instruction to researchers on how to organize documents and submit them to PB.

As a means to instruct researchers and expedite submissions, the HGF/REC institutional website released editable templates of all required instruments, along with the regulatory flow, meeting calendar, answers to the most frequent questions, as well as in-person, email or telephone contact. It also provides a shortcut link to the main relevant legislations, internal regulations, and PB website.

The committee establishes partnerships with all hospital sectors throughout the methodological process, mainly maintaining a close relationship with the Directorate of Education, Research, and Residency, the sector responsible for planning, supervising, guiding, and executing education, improvement, and research activities related to training and capacity-building for human resources in the areas of health care, administration, and support services.

Over half of the studies analyzed presented at least one condition that prolonged the flow time, such as a delay of more than 30 days for researcher response to pending issues. This shows how the lack of adequate records can negatively impact the efficiency and effectiveness of research ethics committees [21].

Quantitative assessment should be continuous and can be associated with qualitative assessment to trace subjective and contextual aspects that influence HGF/REC performance. The use of metrics such as average review time, dispersion, and procedural volume can promote more responsive, transparent, and efficient ethical management.

The CONEP/REC system is still founded on the language of principlist bioethics and an excessively bureaucratic logic, which refers to the "power of the registry office" as a parameter for research ethics. This regulatory structure makes it difficult to adapt qualitative projects to current criteria, imposing methodological and ethical challenges for researchers in the fields of human and social sciences. This criticism shows the need to improve the ethical review system so it can recognize the epistemological and methodological diversity found in different fields of knowledge [10,22].

In 2022, PAHO published *Evaluation tool: indicators for strengthening national research ethics systems* [23], a document that provides guidelines for the use of both quantitative and qualitative indicators, underscoring the need for continuous and broad assessment of research ethics systems. The tool notes that the combination of these data types is essential for tracing subjective and contextual aspects that influence the performance of committees [6,23].

The pursuit of higher efficiency and effectiveness in REC performance has led to the adoption of management tools capable of evaluating and improving their internal processes. The use of performance indicators as a tool to trace critical points in ethical review processes shows that systematic analysis of data related to submitted protocols has not only enabled monitoring the achievement of goals, such as the sixty-day period for approval, but also implementing continuous improvements in committee operation. This approach shows the importance of integrating quantitative assessment

methods into REC management, promoting higher visibility, agility, and quality in ethical decision-making [24].

The adoption of extrapolable research practices has been pointed out as an effective tactic to reinforce the scientific and ethical integrity of studies. RECs should consider requiring that projects allow the replication of results, as a means to ensure data transparency and credibility. This approach not only facilitates independent verification of findings but also contributes to the construction of more solid and reliable scientific knowledge [15,21].

Final considerations

The research showed that, despite presenting a solid structure in more organized stages of the ethical review process, such as the collegiate body work, gaps persist in the initial phases, particularly in document validation. The collected data showed statistically significant differences in average times between these stages, which suggest variable performance that influences the overall efficiency of the process.

The fluctuation observed in the indicators, especially in years marked by the extreme situation of COVID-19 pandemic, proves that different contexts and structures directly impact the operational capacity of the committee. Furthermore, low uniformity in records and, often, lack of data in specific stages hinder evidence-based management and monitoring.

As a result, it is imperative the adoption of strategies for continuously training researchers, valuing work teams, and incorporating technological tools that provide greater workflow automation and standardization. It is fundamental to have a connection between institutional spheres and transparent, fluid communication with researchers, as these elements consolidate the quality of analyses and provide more solid and reliable ethical governance.

By presenting empirical data on the functioning of a large-scale research ethics committee in Brazil, this study contributes to the advancement of the field with practical reflections on ethical management in times of complexity and change. The findings are aligned with international guidelines, such as those proposed by PAHO, and are especially relevant in the context of Law 14,874/2024 [4], which requires committees to adopt a new perspective on their regulatory and operational models.

Given the ever-increasing demands in the field of health research, it is essential that research ethics committees (REC) are not limited to fulfilling formal stages, but rather seek to understand, sensitively and critically, the aspects related to each project. The use of tools that track performance and help trace areas for improvement can make processes more streamlined and consistent with the needs of researchers and society. At the same time, it is necessary to consider the different means of producing knowledge, respecting various trajectories, knowledge, and contexts. More than expediting processes, the objective is to ensure that the ethical review continues to be a space for care, listening, and commitment to the dignity of the people involved in the research.

Finally, it is necessary that future studies adopt mixed methodological approaches, combining time series analysis with qualitative assessment of workflows. This will provide better insights into the conditions that foster efficiency and effectiveness in ethical review. This in-depth approach consolidates the National Research Ethics System, making it even more streamlined, transparent, and committed to the protection of participants and scientific integrity.

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Simone Oliveira Lucas-Bertoldo: study conception and design; methodology development; data request and collection on Plataforma Brasil; data analysis and interpretation; preliminary manuscript drafting; general review and approval of the final version. Adna Braquehais: operational support for research. Luisa Maria Oliveira Pinto: operational support for research. Fred Ribeiro Santiago: operational support for research. Patricia Quirino da Costa: operational support for research. Paula Sacha Frota Nogueira: critical content review.

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