

Trajectory of an ethics committee: 10 years of Plataforma Brasil

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Abstract

This study outlines the profile of the Ethics Committee of the Acaraú Valley State University, Ceará, Brazil, after 10 years of Plataforma Brasil. Bibliographic search surveyed research conducted between 2012 and 2021 according to actors and processes, following descriptive analysis. Results showed a prevalence of female researchers from the health or biological sciences field, and reviewers had a greater academic background, length of experience, and number of projects than researchers. Of the 2,295 studies analyzed, most were approved by 2015, completed in 2016 and under evaluation in 2021, with clear decrease in 2020 and 2021. Original research from national self-funded institutional coordinating centers without thematic area, with a favorable ethical opinion within three months, and reduced flow time between quinquennia stood out. Main ethical obstacles concerned the informed consent and risks. This overview highlights the importance of the platform for scientific progress.

Keywords: Ethics, research. Bioethics. Ethics committees, research. Projects. Health research evaluation.

Resumo

Caminhos de um comitê de ética: 10 anos da Plataforma Brasil

Esta pesquisa buscou traçar o perfil do Comitê de Ética da Universidade Estadual Vale do Acaraú, Ceará, nos 10 anos da Plataforma Brasil. Levantaram-se pesquisas realizadas entre 2012 e 2021, conforme atores ou processos, seguindo a análise descritiva. Houve prevalência feminina e do campo da saúde ou ciências biológicas, e pareceristas tiveram maior formação acadêmica, tempo de experiência e número de projetos em relação a pesquisadores. Das 2.295 pesquisas analisadas, houve flutuações temporais, com concentração de projetos anteriormente aprovados até 2015, finalizados em 2016 e em trâmite em 2021, com evidente diminuição em 2020 e 2021. Foram mais frequentes pesquisas originais de centros coordenadores, institucionais, brasileiras, autofinanciadas, sem área temática, com decisão ética favorável, em até três meses e tempo de fluxo reduzido entre quinquênios. Termo de consentimento livre e esclarecido e riscos destacaram-se como principais óbices éticos. Esse panorama valoriza a importância da plataforma para o progresso científico.

Palavras-chave: Ética em pesquisa. Bioética. Comitês de ética em pesquisa. Projetos. Avaliação da pesquisa em saúde.

Resumen

Trajectory of an ethics committee: 10 years of the Plataforma Brasil

Esta investigación rastreó el perfil del Comité de Ética de la Universidad Estadual Vale do Acaraú, Ceará, Brasil, en los 10 años de la Plataforma Brasil. Los estudios ocurrieron entre 2012 y 2021 según actores o procesos, siguiendo el análisis descriptivo. Predominaron mujeres del campo de la salud o las ciencias biológicas y, comparados con los investigadores, los árbitros tenían alto nivel de formación académica, mayor tiempo de experiencia y proyectos. En 2.295 estudios hubo fluctuaciones temporales, con concentración de proyectos aprobados hasta 2015, completados en 2016 y en curso en 2021, con disminución evidente entre 2020-2021. Los estudios más frecuentes provienen de los centros coordinadores, institucionales, brasileños, autoapoyados, sin área temática, con decisión ética favorable hasta tres meses y tiempo de flujo reducido entre quinquenios. El formulario de consentimiento y los riesgos fueron los principales obstáculos éticos. Este panorama valora la importancia de la plataforma al progreso científico.

Palabras clave: Ética en investigación. Bioética. Comitês de ética en investigación. Proyectos. Evaluación de la investigación en salud.

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Bioethics is a transversal component in scientific research, guided by Resolutions 466/2012¹ and 510/2016², of the National Health Council (CNS), which highlight a respect for the principles of non-maleficence, beneficence, autonomy, justice, and equity, as well as to other regulations, given its adherence to multiple scopes. Analysis by a multidisciplinary and independent collegiate is mandatory to protect research participants and diligently respond to protocols forwarded by researchers from institutions or companies, ensuring the effectiveness and fairness of opinions^{3,4}.

In Brazil, human subject research must be evaluated under the aegis of bioethics and previously authorized by research ethics committees (CEP), local instances for less complex protocols, whose capillarity reaches 98% of submissions, or the National Ethics Commission in Research (Conep), a national body under the Ministry of Health (MS) for special theme areas of greater complexity and responsible for updating guidelines and regulations^{1,3}. To have a real dimension of this coverage, by October 2022, Brazil had 875 CEPs, with 190 in the Northeast region and 42 in the state of Ceará^{4,5}.

The CEP/Conep system was instituted by the revoked Resolution CNS 196/1996⁶ and underwent a significant management evolution, transitioning from the conventional physical to the electronic model⁷. The first online platform in the country was the National System of Information on Ethics and Research (Sisnep), which operated from 2002 until the end of 2011. It allowed for the registration of general project data, issuing of cover sheets, and monitoring of their approval, but did not store all the documental and procedural data referring to each research project⁷.

As of 2012, Sisnep's semi-computerized platform was replaced by Plataforma Brasil, enabling registration, monitoring, notifications, and various interactions in a transparent, traceable, agile, and fully online system. As a result of the improvement of the system via artificial intelligence, its third version also presents a virtual assistant⁸. The advent of this national and unified base reduced physical bureaucracy and long evaluation times, which were the main complaints of the academic community, acting as a more effective social control tool,

enabling the regularity monitoring by both researchers and participants⁹.

Despite offering open access functionalities and bypassing the need for registration to search for information, Plataforma Brasil is not devoid of limitations and has not allowed over the last decade for an automatic detailed analysis of research specificities, such as scope, elapsed time, and major reasons for pending issues, as well as the human aspects of the collegiate bodies that make up the CEP/Conep system⁸. The management of evaluation flows and the teams that makeup CEPs in the country is a scarce subject in the literature, with little evidence on strong points and aspects to be improved, which could contribute to the reflection and maturation of the CEPs⁴.

The scenario proposed for this case study was the Human Research Ethics Committee of the Acaraú Valley State University (CEP/UVA), established in October 2002 at the UVA Health Sciences Center, in Sobral, in the inland Ceará¹⁰, and continuous activity registered by Conep⁸. In its trajectory, CEP/UVA polarized research at the loco-regional level in the countryside, given it is located 232 km from the capital Fortaleza, having already hosted professors from different fields of knowledge and user representations nominated by the Municipal Health Council of Sobral¹⁰. As a pioneer in the city, CEP/UVA collaborated as a training center for the CEPs of two institutions: Santa Casa da Misericórdia de Sobral Hospital (CEP/SCMS), in 2016¹¹, and Centro Universitário Instituto Superior de Teologia Aplicada (CEP/Uninta), in 2017¹².

Given the gaps in knowledge on the subject, this study sought to outline an overview of the CEP/UVA to identify advances and challenges after 10 years of Plataforma Brasil in managing the bioethical procedures of the CEP/Conep system.

Method

The research scenario was the CEP/UVA itself, using its electronic document base through CEP's interface on Plataforma Brasil⁸, accessible for the researcher's referee registration. The sample consisted of all projects previously evaluated or under evaluation between the consolidated years of 2012 and 2021.

A remote survey of the sample was carried out, analyzing substantiated opinions issued by either the CEP or Conep, as well as the history of procedures, which allowed for the categorization of research projects according to the actors or processes involved.

The total of researchers and reviewers were quantified separately in the dimension of actors in the decennial interstice, proceeding to their classification according to gender, title in initial contact with Plataforma Brasil, the field of knowledge according to the National Council for Scientific and Technological Development (CNPq), total years of experience with the platform, and average projects submitted or reviewed each year, respectively.

Within the dimension of processes in the decennial interstice, the surveys were quantified according to type (project, amendment or notification, coordinating center, participants, or co-participants), proposing institution (either from or outside the CEP), country (Brazilian or foreign), funding (either own or institutional), Conep's special theme area (sent by the researcher or at the CEP's discretion), ethical decision (approved; refused, withdrawn or not approved; pending; in reporting; in flow with Conep; or another) and time flow (from submission to a final decision, in ranges of days and

overall average, or per five-year period). Finally, a general classification and quantification of the main ethical and documental obstacles recorded during the entire period analyzed was carried out.

The collected information was tabulated using Microsoft Excel software for the analysis of the variables and underwent simple descriptive analysis, using both absolute and relative values (percentages) or mean±absolute deviation from the mean.

Complementarily, the current composition of the CEP/UVA, available for public access on an institutional website¹⁰, was investigated to determine the profiles of the reviewers' fields of action.

Results

Table 1 shows that the higher prevalence of females and the area of knowledge in health or biological sciences concerning the other categories was similar between researchers and reviewers. Academic education at the graduate level (master's or doctorate) surpassed two-thirds of the sample of reviewers, and over half of the researchers had a specialization degree.

Table 1. Profile of actors in CEP/UVA surveys from 2012 to 2021

Categories	Researchers (n=849)	Anonymous reviewer (n=51)
Gender	♀: 581 (68.43%) ♂: 268 (31.57%)	♀: 32 (62.75%) ♂: 19 (37.25%)
Title to initial contact with Plataforma Brasil	D: 119 (14.02%) M: 239 (28.15%) E: 319 (37.57%) G: 172 (20.26%)	D: 27 (52.94%) M: 14 (27.45%) E: 5 (9.80%) G: 5 (9.80%)
Knowledge area	CSB: 632 (74.44%) CHSA: 118 (13.90%) O: 99 (11.66%)	CSB: 32 (62.75%) CHSA: 13 (25.49%) O: 6 (11.76%)
Years of experience with Plataforma Brasil	1.51±0.77	3.18±1.73
Mean±absolute deviation from the average of projects per year	1.48±0.69	9.25±5.01

CEP/UVA: Ethics Committee for Human Subject Research of Acaraú Valley State University; D: doctorate; M: master's degree; E: specialization; G: graduation; CSB: health or biological sciences; CHSA: applied humanities or social sciences; O: other

Reviewers had twice the mean total experience with Plataforma Brasil when compared to the researchers. Most of the former (35; 68.63%)

remained in the activity for up to three years, while most of the latter (638; 75.15%) had contact with the activity for up to one year.

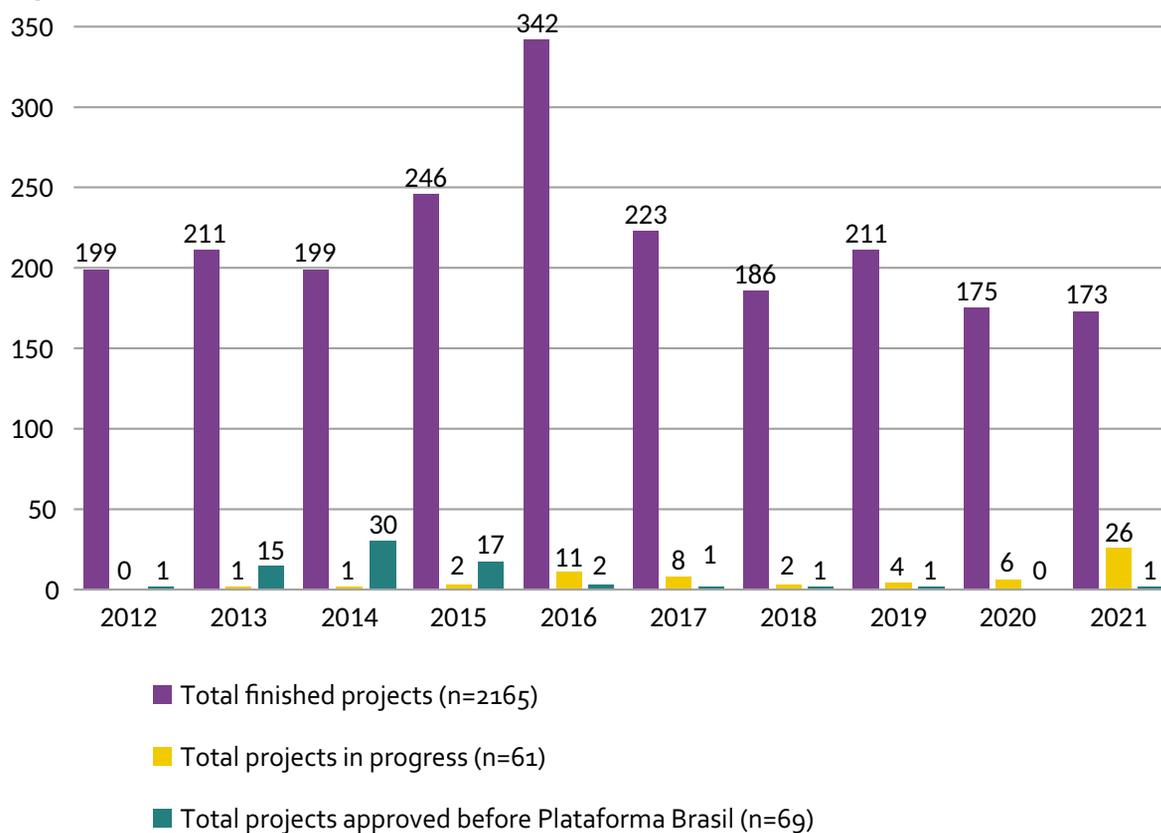
The average number of projects analyzed or under analysis by reviewers exceeded six times the average of projects sent annually by researchers, with most reviewers (30; 58.82%) evaluating up to nine projects per year, while most of the researchers (604; 71.14%) submitted up to one project per year.

Regarding the most recent composition of the CEP/UVA, 13 reviewers in practice were registered by December 2021, with training in administration, social sciences, physical education, nursing, medicine, dentistry, pedagogy, psychology,

and chemistry, reinforcing the multidisciplinary nature of the collegiate.

Figure 1 shows the temporal evolution of the total number of surveys processed at CEP/UVA via Plataforma Brasil. Projects approved before the creation of the platform were more frequently registered between 2013 and 2015, and there was a significant peak of fully analyzed projects in 2016, with the lowest number of the entire decade being in 2020 and 2021. Projects in progress were more abundant in 2021, although retroactive years also showed small frequencies.

Figure 1. Temporal evolution of research in CEP/UVA from 2012 to 2021 (n=2,295)



CEP-UVA: Ethics Committee for Human Subject Research of Acaraú Valley State University

Table 2 describes the profile of projects in CEP/UVA according to categories and results, with original research projects being more frequent in relation to amendments and notifications, as well as coordinating centers concerning (co)participating centers. In half of the sample,

the proposing institution was UVA itself, with the remaining portion made up of 27 institutions from the same municipality, which did not have their own CEP until then, with emphasis to Centro Universitário Uninta (537; 23.40%) and Santa Casa de Misericórdia de Sobral (164; 7.15%).

Table 2. Profile of CEP/UVA projects from 2012 to 2021 (n=2,295)

Categories	Results
Research type	Coordinating center's original project: 2,104 (91.68%) (Co)participant center's original project: 56 (2.44%) Coordinating center's amendment: 42 (1.83%) (Co)participant center's amendment: 16 (0.70%) Coordinating center's notification: 55 (2.40%) (Co)participating center's notification: 22 (0.96%)
Proposing institution	From the CEP itself: 1,130 (49.24%) Other than CEP: 1,165 (50.76%)
Country	Study in Brazil: 2,291 (99.83%) International study: 4 (0.17%)
Financing	From the researcher themselves: 2,151 (93.73%) Institutional: 144 (6.27%)
Special theme area	No: 2,244 (97.78%) Yes (human genetics): 8 (0.35%) Yes (new equipment and devices): 8 (0.35%) Yes (biosecurity): 7 (0.31%) Yes (new procedures): 6 (0.26%) Yes (originated outside of Brazil): 5 (0.22%) Yes (human reproduction): 3 (0.13%) Yes (indigenous populations): 3 (0.13%) Yes (new drugs, vaccine, and diagnostic tests): 2 (0.09%) Yes (at CEP discretion): 9 (0.39%)
Ethical decision	Approved: 1,698 (73.99%) Rejected, discontinued, or not approved: 342 (14.90%) Pending: 170 (7.41%) In reporting: 30 (1.31%) In flow with Conep: 27 (1.18%) Transferred, in documentary, or rapporteur validation: 28 (1.22%)
Flow time	1-30 days: 535 (23.31%) 31-60 days: 452 (19.69%) 61-90 days: 367 (15.99%) 91-120 days: 330 (14.38%) 121-180 days: 296 (12.90%) 181-365 days: 213 (9.28%) Over 365 days: 102 (4.44%)

CEP/UVA: Ethics Committee for Human Subject Research of Acaraú Valley State University

Brazilian research predominated, with only four transnational multicenter protocols based in the United Kingdom. The researcher's own funding was 15 times more frequent than institutional funding, with public sources (111; 4.84%) being more common than private sources (33; 1.44%).

The frequency of research directed at Conep in the special theme areas registered in the submission was low, with an increase in referrals at the discretion of the CEP from 2020—COVID-19 (6; 0.26%) and biobank (3; 0.13%). Favorable ethical

decisions were predominant, while non-approved categories added up to a quarter of the sample. The flow time pointed to a higher prevalence in the range of up to 30 days, with over half of the general sample reaching up to three months.

In a frequent analysis of the flow time considering the sample and the total period, the average was 110.09±84.53 days. When considering a temporal stratification by five years periods from the submission date, the sample between 2012 and 2016 (n=1,277) reached an average of

125.51±96.23 days, and the sample from 2017 to 2021 (n=1,018) had an average of 90.78±69.10 days. Thus, there was a progressive reduction in flow time over the analyzed decade.

Records of more than one project evaluation version, exchange of reviewers, or delays of more than 30 days for the researcher to return pending issues were typical findings in flows past 60 days. Over half of the sample (1,308 surveys or 56.99% of the total) presented at least one of the conditions described.

Table 3 highlights the main reasons for rejection, pending, or exceptions to the projects analyzed by CEP/UVA. The absence or non-compliance of documents sent to Plataforma Brasil resulted in ethical obstacles in which the informed consent form (ICF) had greater representation through institutional consent, schedule, cover page, data collection instrument, detailed project, budget, term of consent, term of trustee, and term of use of image and testimonials.

Table 3. Ethical or documentary obstacles in research at CEP/UVA from 2012 to 2021 (n=2,295)

Item	Frequency (one or more items per project)
ICF	1,080 (47.06%)
Institutional approval	773 (33.68%)
Timeline	591 (25.75%)
Title page	367 (15.99%)
Risks	354 (15.42%)
Data collection instrument	309 (13.46%)
Detailed project	230 (10.02%)
Sampling	159 (6.93%)
Benefits	141 (6.14%)
Budget	136 (5.93%)
Term of consent	95 (4.14%)
Approach to the participants	94 (4.10%)
Justification for ICF's absence	37 (1.61%)
Trustee Term	36 (1.57%)
Framing in a special theme area	35 (1.53%)
Steps or Interventions to be performed	34 (1.48%)
Term of use of images and testimonials	10 (0.44%)
Data analysis	7 (0.31%)
Title	6 (0.26%)
Objectives	4 (0.17%)

CEP/UVA: Ethics Committee for Human Subject Research of Acaraú Valley State University; ICF: informed consent form

When analyzing specific items, the absence or lack of clarity of risks and their minimization strategies had a greater impact than the deficiencies in sampling description (such as the number of volunteers and their inclusion and exclusion criteria, including groups, age group, and gender), benefits, approach to participants (virtual or face-to-face, ignoring health precautions during the pandemic), justification for ICF absence, framing in a special theme area (only seven suitable surveys, including three of indigenous populations and four of foreign origin), steps or interventions to be carried out, data analysis, title, and objectives.

Discussion

The expressive number of research in the field of health or biomedical converges into the expected, according to the scope of human subject research¹, although the area of applied human and social sciences seems to be the most popular, reaching 42% of the total proposals in a CEP in Paraíba¹³, a number significantly higher than that found in Ceará's CEP.

The highest number of projects submitted by researchers, associated with the lowest degrees, is similar to the findings of the study by Silva and Santos¹³, in which over half of the actors were masters and presented a single protocol. Such a profile may suggest linking research to postgraduate studies in progress and a typical period with more active scientific production¹⁴ compared to studies oriented to undergraduate medicine, with only 13.5% of the research submitted to a CEP in Minas Gerais¹⁵.

The greater number of projects analyzed by reviewers may reflect the desirable experience for a multidisciplinary collegiate, performing the efficient analysis of proposals diverse in content³. Female members from the field of biological sciences, with a doctorate, professional experience equal to or greater than 30 years, and participation in an event or course on research ethics were prevalent in four CEPs in Bahia. This corroborates the hypothesis that a higher academic degree and experience can favor a more accurate bioethical assessment¹⁶.

The current total of CEP/UVA rapporteurs was slightly lower than the national average of 16 members per CEP able to provide substantiated opinions, considering coordinators, reporting members, and representatives of research participants⁵.

The amount of research analyzed by the CEP/UVA is close to the average of 200 projects per year found on a CEP in Espírito Santo¹⁷, surpassing a CEP from Pará, with 633 projects in five years (from 2006 to 2010)¹⁸, and a CEP from Paraíba, with 228 in seven years (from 2008 to 2014)¹³, which suggests discrepancies between Brazilian regions and the contribution arriving from each teaching and research institution. The temporal evolution of the CEP corroborates the continuous transformation in the ethical review system in research in the country¹⁹.

The trend in the first years of the decade of registering research approved before the release of Plataforma Brasil reflects the transition period of the old project management model via Sisnep⁷. The increase in projects from 2016 may be related to the increase in regulatory resolutions involving research in human sciences², clinical cases²⁰, or priority topics for the Unified Health System (SUS)²¹. The smaller amount of research from 2020 onwards can be associated with the negative impact of the COVID-19 pandemic, which initially limited academic production due to social isolation⁴, but, on the other hand, improved the virtual data collection for more recent studies²².

The profile of original research projects corroborates literature, being more frequently associated with studies to obtain an academic title than to funded works¹⁵. Although Plataforma Brasil operates from the design phase to the submission of reports⁹, the low number of notifications demonstrates the limited feedback of the system by the academic community itself.

A survey in a CEP in Espírito Santo showed that observational or intervention studies focusing on health care for workers, women, adolescents, children, and the elderly, were more frequent than experimental studies and those of high technological complexity¹⁷, similar to the low frequency found from special theme areas, despite the increase in studies on COVID-19⁴. However, the low association between institutions for the execution of joint projects points to a further endogenous pattern, even if shy, for the advancement of multicentric research or of international permeability⁹.

Even though Plataforma Brasil is a national and unified base for registering research, allowing it to interact with regulatory and development

agencies⁹, the prevalence of self-financing in this study exposes the brutal lack of sponsorship faced by researchers.

In Brazil, human subject research is underfunded, despite its obvious strategic importance for the country's development⁴. The ethical decision standard is close to that of a CEP in Paraíba, where 82.02% of the surveys were approved¹³.

Researchers and institutions must value the committee's tasks, allowing adequate time for collegiate assessments and avoiding reviewers' exchanges, which would cause delays in the flow of projects²³. Also, longer processing of projects could be related to high demand, addenda, scope complexity, or withdrawal by the researcher, factors that substantially extend the time to fulfill the analysis^{19,23}.

The pendency of a CEP in Pará reached 86.5% of the projects, with mistakes being more prevalent in the ICF¹⁸, which is in line with the findings of this study. Over half of the research projects submitted to CEPs for institutional development in medicine or nursing courses in the countryside of São Paulo had errors in filling out mandatory documents²⁴.

Another CEP from Pará verified that the projects were attentive to beneficence and patient autonomy, but lacked both justice and secrecy, with a slow improvement in such principles over the years²⁵. Research carried out in different dentistry courses in Brazil also showed weaknesses regarding the ICF, in terms of the right to anonymity and authorization to use data and images²⁶.

The clarity in the objective, language, and presentation of the ICF contributes to good compliance with the foreseen ethical and legal requirements²⁷. Clinical approaches may have been hindered by the non-preservation of the right to privacy and confidentiality in hospitalized individuals with reduced autonomy, reinforcing the need for a careful look at the construction of the project, to avoid invasive situations or uncritical acceptance of the care to be received²⁸.

In the research protocols, a CEP from Minas Gerais verified that the description of risks was present in only a quarter of the forms or the ICF, while prevention measures comprised over half of the corresponding documents, evidencing the difficulty of the researchers in identifying potential harm in human research²⁹.

Inadequacies in the sample size or analysis methods to answer the questions studied are also a common reason for pending³⁰.

It is worth reinforcing the relevance of the CEPs as an advisory and educational instance for research practice^{9,18}. Continuous training programs are useful for both reviewers and researchers, but their implementation, development, and consolidation call for greater support and institutional investment^{16,19}.

There is little or no caution about scientific integrity, publicity, encouragement of research, plagiarism, and data manipulation in curriculum guidelines and codes of ethics in the fields of medicine, nursing, pharmacy, nutrition, dentistry, and biomedicine. Greater ethical and methodological commitment in health education is, thus, paramount to the re-establishment of good scientific practices³¹.

About a quarter of medical and nursing students who participated in research projects submitted to a CEP in the countryside of São Paulo affirmed having received insufficient information from their advisors regarding the documents and fundamental bioethical aspects for processing in Plataforma Brasil, nearly unanimously pointing to the need for the insertion of bioethics into the curriculum²⁴.

Although university professors in Paraíba perceive CEP's institutional role in protecting participants and authorizing publications as a positive one, they often misunderstand the evaluation process, as well as the meaning of recommendations in light of current regulations³². Unusual areas of evaluation, such as research

involving children, indigenous peoples, genetics, new drugs, and invasive procedures, also reinforce the need for constant updating by CEP members to issue adequate substantiated opinions³³.

CEP leaders in Brazil converge on the critical points for improving bioethical human subject assessments with greater representation of users, aiming at the protection of participants; parsimony in institutional managers' actions to avoid conflicts of interest; a core agenda to prevent excessive administrative demands for its members; and the need for better training in research ethics³³.

Despite the obstacles regarding the standards of analysis in the various committees, and the difficulties in monitoring ongoing projects and registering on Plataforma Brasil, the Brazilian system is a benchmark for other countries. This is due to its effective structuring, respect, and protection of research participants and inclusion of society within the scope of the committees^{33,34}.

Final considerations

With the implementation of Plataforma Brasil, advances, and challenges have permeated CEP/UVA's paths over the last decade, considering similarities or differences in the dimensions of actors and processes regarding other CEPs in the country. This scenario highlights the key role of the platform for scientific progress and motivates future discussions on research management in the country.

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Igor Iuco Castro-Silva conceived the study, collected and analyzed the data, wrote the article, and carried out its critical review. Elciane Maria do Nascimento and Ana Carolina de Oliveira Portela collected and analyzed the data. Jacques Antonio Cavalcante Maciel wrote the article and carried out its critical review.

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