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EVOLUTION AND IMPORTANCE OF THE RESEARCH ETHICS COMMITTEE, CEP, IN HIGHER EDUCATION INSTITUTIONS: A STUDY IN A WESTERN AMAZONIAN INSTITUTION BETWEEN 2018 TO 2022

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Abstract: The Research Ethics Committee (CEP) has become an essential mechanism for social control in Brazilian research involving human subjects, contributing to the development of studies guided by ethical standards and to the protection of research participants. This article analyzes the performance of CEP in Western Amazonian institution, its history, operating conditions, trends, and different aspects between 2018 to 2022. The theoretical framework addresses the history of research involving human subjects, the origins and evolution of bioethics in the international context, bioethics in Brazil, and regulations on the ethical analysis of research. The data were collected through the Brazil Platform and reports from the institution's CEP. The CEP evaluated 865 research protocols, most of which were from Health Sciences. Additionally, it was observed that during 2018 to 2022 the covid-19 pandemic had a negative impact on the number of projects submitted for evaluation to the CEP. The 57% drop in the number of projects registered during 2020/2022 reveals the negative impact of this event on the execution of projects with human participants.

Keywords: research ethics committee, ethical norms and standards, research subjects and participants, covid-19

Evolución e importancia del Comité de Ética en Investigación, CEP, en instituciones de enseñanza superior: un estudio en una institución de la amazonia occidental entre 2018 y 2022

Resumen: El Comité de Ética en Investigación (CEP) se ha convertido en un mecanismo esencial para el control social en la investigación brasileña con seres humanos, contribuyendo al desarrollo de estudios guiados por normas éticas y a la protección de los participantes en la investigación. Este artículo analiza el desempeño del CEP en la institución amazónica occidental, su historia, condiciones de funcionamiento, tendencias y diferentes aspectos entre 2018 y 2022. El marco teórico aborda la historia de la investigación con seres humanos, los orígenes y la evolución de la bioética en el contexto internacional, la bioética en Brasil y la normativa sobre el análisis ético de la investigación. Los datos se recogieron a través de la Plataforma Brasil y de informes del CEP de la institución. El CEP evaluó 865 protocolos de investigación, la mayoría de los cuales eran de Ciencias de la Salud. Además, se observó que durante 2018 a 2022 la pandemia de covid-19 tuvo un impacto negativo en el número de proyectos presentados para evaluación al CEP. La caída del 57% en el número de proyectos registrados durante 2020/2022 revela el impacto negativo de este evento en la ejecución de proyectos con participantes humanos.

Palabras clave: comité de ética de la investigación, normas y estándares éticos, sujetos y participantes en la investigación, covid-19

Evolução e importância dos Comitês de Ética em Pesquisa - CEPs em instituições de ensino superior: um estudo em instituição amazônica ocidental entre 2018 e 2022

Resumo: Os Comitês de Ética em Pesquisa (CEPs) tornaram-se um mecanismo essencial para o controle social em pesquisas brasileiras envolvendo sujeitos humanos, contribuindo para o desenvolvimento de estudos regido por padrões éticos e para a proteção de participantes de pesquisas. Esse artigo analisa o desempenho de CEP em instituição da Amazonia Ocidental, sua história, condições operativas, tendências e diferentes aspectos entre 2018 e 2022. O enquadre teórico visa a história da pesquisa envolvendo sujeitos humanos, as origens e evolução da bioética no contexto internacional, bioética no Brasil e regulamentos de análise ética de pesquisa. Os dados foram coletados através da Plataforma Brasil e relatórios do CEP da instituição. O CEP avaliou 865 protocolos de pesquisa, a maioria deles de Ciências da Saúde. Adicionalmente, foi observado que de 2018 a 2022 a pandemia da covid-19 teve um impacto negativo no número de projetos submetidos para avaliação do CEP. A queda de 57% no número de projetos registrados em 2020/2022 revela o impacto negativo desse evento na execução de projetos com participantes humanos.

Palavras-chave: comitê de ética em pesquisa, normas e padrões éticos, sujeitos e participantes de pesquisa, covid-19

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Introduction

The Northern region of Brazil encompasses one of the largest biomes in the world, consisting mostly of the Amazon Rainforest. Despite the Brazilian government's strong territorial occupation efforts in the latter half of the 20th century, which presented the region as a land of riches with opportunities for all to enjoy, it was later realized that the geopolitical plan for the region had neglected better control over the area's wealth, biodiversity, and the knowledge of traditional peoples due to both geographic and human occupation issues*(1)*. As a result, the region is often targeted by illegal occupation practices, which often result in conflicts with native communities or between those who seek to appropriate the region's resources*(2)*. The region also suffers from the biopiracy of its fauna and flora and the inappropriate appropriation of indigenous knowledge*(3)*.

In the latter half of the 1990s, Brazil developed a system to safeguard research involving human subjects named CEP/CONEP system. This system is formed by the Health National Council (CONEP) and Research Ethics Committees (CEP)*(4)* and was created to defend the principles of bioethics and ensure their adherence.

This article aims to examine the research landscape in Western Amazonia by investigating a Research Ethics Committee with Human Subjects at a local institution. We will explore the types of investigations that fall under the purview of CEPs, the role of Committees as a mechanism for social control, and the current legislation governing research involving human subjects. Furthermore, we will discuss how the creation of the CEP/CONEP system*(4)* contributes to the protection of biodiversity in the advancement of science and medicine.

Ethics committees in research at higher education institutions

Since the 1990s, Ethics Committees in Brazil have experienced significant growth, particularly in research institutions, universities, hospital systems, and other related institutions. This trend began with the establishment of the CEP/CONEP system in 1996 through CNS Resolution No. 196*(5)* on October 10th of that year. The CEP/CONEP system has continued to expand, leading to a surge in the number of CEPs throughout the Brazilian territory.

In 1997, there were 84 registered CEPs in Brazil. By 1998, this number had increased to 128 and had skyrocketed to 500 by 2006, according to Costa*(6)*. Over the ten-year period from 2007 to 2017, the number of registered CEPs climbed to 791*(6-8)*. As of May 2022, there are currently 871 registered and active CEPs in Brazil, according to CONEP*(8,9)*. The distribution of these CEPs by region is shown in Figure 1 below, which also displays the number of individuals involved in Brazilian CEPs.

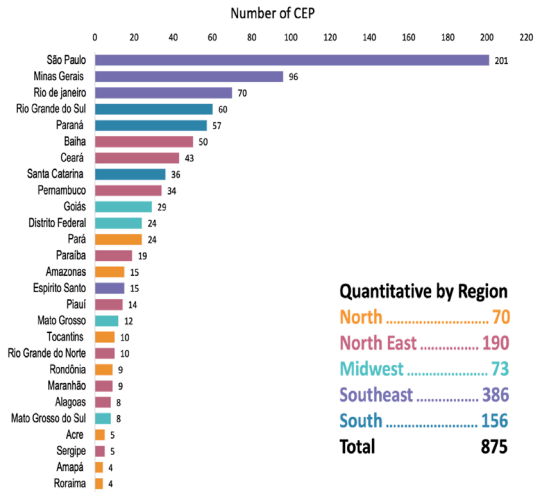


Figure 1. Ethics Committees in Brazil by State and Region. Source: CEP/CONEP System, CEP Management. CONEP, 2022. Data up to May 2022*(10)*.

An essential aspect of this process is the comprehension of the individuals and professionals involved in defending the rights of research participants. They work in support of volunteers who provide researchers with various types of information. According to Resolution No. 466/2012*(11)* and MS/CNS/CONEP No. 510/2016*(12)*, these participants are individuals who, either voluntarily or with the informed consent and approval of their legal guardians, agree to participate in research*(13)*.

Research participation should be free of charge,

and the dignity of the subject/participant should be respected while acknowledging their vulnerability and willingness to contribute. Participants must be fully informed and have the right to withdraw from the research at any time. These initial clarifications are essential since it is vital to respect the dignity of those who possess the information and are willing to share it in a research project. Protecting the participant (voluntary subject) in research is the primary objective of all CEPs/CONEP, with their active research members working to achieve this goal through compliance with established norms and regulations*(13)*.

The longest-standing regulation is Resolution No. 196/1996*(5)*, which established the CEP system and informed consent through the Free and Informed Consent Form (FICF), the National Commission for Ethics in Research (CONEP), and the fundamental bioethics concepts of autonomy, non-maleficence, beneficence, and justice. It is considered a significant milestone in research involving humans since it mandates that all research involving humans, whether direct or indirect, should be subjected to analysis by an ethics committee. This criterion has a broad scope, including health sciences, as well as human and applied social sciences*(13)*.

A brief history of the standardization of ethical analysis of research in Brazil reveals that Resolution No. 01/1988*(14)* from the National Health Council (CNS) was the first official Brazilian document aimed at standardizing research in the health field. The Ministry of Health, seeking to regulate the practice of investigative activity, ratify the global reflections related to scientific advances and their impact on human life, and provide conditions for the imposition and operationalization of ethical principles, reaffirmed the Declaration of Helsinki and the International Guidelines. The CNS edited the resolution in 1988*(15)*.

The Ministry of Health, in its initial interests of ratifying global reflections related to scientific advancement and its impact on human life, regulating the practice of investigative activity and providing conditions for the imposition and operationalization of ethical principles, reaffirming the Declaration of Helsinki and the International Guidelines, issued Resolution No. 01 through its National Health Council (CNS) in 1988*(15)*.

The 1990s marked a significant turning point for ethical considerations in research in Brazil, with the introduction of a new set of regulations aimed at guiding ethical considerations in research. This new document mandates that all research involving human subjects, whether directly or indirectly, not just those in the biomedical field, must be presented for approval by a research ethics committee. In addition, this resolution provides for the establishment of CEPs (*Comitês de Ética em Pesquisa* or Research Ethics Committees) at institutions conducting research involving human subjects*(5)*.

> VII.1 - Institutions that conduct research involving human subjects must establish one or more Ethics Committees for Research - CEP as required. VII.2 - If it is not feasible to establish a CEP, the institution or responsible researcher must submit the project for review to a CEP from another institution, chosen from those listed by the National Commission of Ethics in Research*(5)*.

In a continuous process of evaluation, national and subnational meetings are promoted by CONEP and/or CEPs themselves to bring advances in science into regulations. After almost 17 years, Resolution No. 196*(5)* was revoked and replaced by Resolution No. nº466/2012 through a broad process of discussion and construction. According to this Resolution (VII.2), CEPs are:

> [...] interdisciplinary and independent collegial bodies of public relevance with a consultative, deliberative, and educational role created to safeguard the integrity and dignity of research participants and promote research development in accordance with ethical standards*(11)*.

Resolution 466/2012*(11)* outlines the following responsibilities for research ethics committees:

> VIII.1 - Evaluate research proposals involving human subjects, giving priority to topics of public relevance and strategic interest of the SUS priorities agenda based on epidemiological indicators. They should issue a duly justified opinion, always guided by principles such as impartiality, transparency, reasonableness, pro-

> portionality, and efficiency. Operational norms should establish deadlines for review, and redundancies should be avoided to prevent delays in analysis; VIII.2 - Perform a consultative and educational role in ethical issues; VIII.3 - Develop their own Internal Regulations.

In addition to evaluating research protocols, the CEP is also responsible for promoting study monitoring through biannual reports or other methods based on the level of research risk*(11)*. The CEP also develops educational activities, updates CEP members and the community, and monitors the progress of approved research projects. With Resolution No. 466/2012, the CEP/CONEP system has been strengthened, resulting in a more rigorous analysis of submitted projects.

It's important to emphasize that the CEP is an autonomous, multidisciplinary, and collegiate deliberative body, connected to the highest authority in the institution. The institution must provide the necessary means for its operation while preserving the CEP's autonomy in relation to the decisions made by its members. Ultimately, the CEP is responsible for ensuring the ethical protection of research participants. As such, all research involving human subjects must be submitted for review by the institution's Ethics Committee to safeguard the participants' rights and ensure that the research is conducted according to ethical standards. These committees are responsible for conducting ethical evaluations of any research project involving human subjects, whether directly or indirectly if it adheres to recognized methodological and scientific standards and is registered by the researchers.

During the submission process to the CEP, the project goes through several steps. The first step is for the responsible researcher to include it in Plataforma Brasil*(8)*, a Brazilian electronic system created by the Federal Government to streamline the receipt of research projects involving human subjects by Ethics Committees throughout the country. Its implementation was in 2012, replacing the former National System of Information on Ethics in Research Involving Human Beings (Sisnep), which operated from 1996 to 2012.

Therefore, Plataforma Brasil*(8)* serves as the gateway for project submission, as:

> [...] is a national and unified database of records of research involving human subjects for the entire CEP/Conep system. It allows research to be tracked at different stages - from submission to final approval by CEP and Conep, when necessary - enabling even the monitoring of the field phase, the submission of partial reports, and final reports of the research (when completed). The system also allows documents to be presented digitally, providing society with access to public data of all approved research. Through the internet, all involved parties can access information in a shared environment, significantly reducing the processing time of projects throughout the CEP/Conep system*(8)*.

After submitting the project on Plataforma Brasil*(8)*, the system generates a cover sheet with the title and information of the responsible researcher. The sheet must be dated and signed by the researcher and filled out and signed by the institution's representative. Once the cover sheet is properly filled out, the researcher must return to Plataforma Brasil*(8)* to attach it, along with other mandatory documents as per current regulations. These documents include the research project, IC/AF - Informed Consent/Assent Form, authorization from the research site, execution schedule, detailed financial budget, and commitment letter from the responsible researcher, among others*(16)*.

After submission, the documentation is reviewed by the secretary, and the local CEP coordinator is responsible for validating it. In the event of missing or incomplete information, the project is returned to the researcher for correction. Once the documentation is validated, the research project is assigned to a CEP member designated by the coordinator for ethical evaluation. During the CEP's regular meeting, the projects and their respective evaluations are presented to all members for consideration. After discussion, the rapporteur's evaluation is voted on, which can be for approval, pending, or not approved. Any pending issues must be resolved within 30 days of the release of the evaluation by the researcher and returned to the CEP for further review. If not approved, the researcher may resubmit the project, provided new facts are presented, and necessary adjustments are made*(16)*.

At the conclusion of the review process by the board of reviewers, the CEP provides substantiated opinions on the ethical aspects of research activities involving human subjects, considering the potential impact of such activities on the well-being and fundamental rights of individuals and human populations. After considering these aspects, the CEP authorizes the execution of the reviewed project. It is important to note that the CEP does not review projects that are already underway or executed without prior ethical review, except in cases of clinical findings where the activity has already been carried out*(16)*.

When it comes to vulnerable populations, as well as others, they receive support from the Resolutions that govern the activities of Ethics Committees, and research projects undergo dual analysis from both local Ethics Committees and the National Research Ethics Commission - CONEP. It is crucial to emphasize that participation in research is voluntary, and participants retain the right to withdraw their consent if they feel that their dignity is being compromised, as established by the National Health Council. For research to be considered ethical, it must meet the following requirements:

> To respect the dignity and autonomy of research participants, it is important to acknowledge their vulnerability and ensure that they are willing to contribute to the research, or not, through expressed, free, and informed consent. Balancing the known and potential risks and benefits, whether individual or collective, is crucial to ensuring maximum benefits and minimum harm and risks. It is also essential to avoid foreseeable harm and ensure that the research has social relevance, which requires equal consideration of all interests involved while maintaining its humanitarian and social purpose*(10)*.

Ethics committees also serve as reporting channels for violations and can intervene if they perceive that research does not respect the guarantees provided to the participants. When working with traditional populations, it is important to fully respect their culture, including seeking the consent of local leadership for researchers to enter the research field. Although ethical analysis resolutions for research require this procedure, it has not prevented individuals from entering these communities and appropriating local knowledge in violation of legal norms*(16)*.

Ethics committee housed at Aparicio Carvalho University Center – CEP-12

The Research Ethics Committee of the Centro Universitário Aparício Carvalho – FIMCA (initially as CEP/FIMCA), was established internally on November 18, 2005. The CONEP approved the CEP/FIMCA on April 10, 2006, and renewed it on September 9, 2009. It undergoes a re-accreditation process every three years, developing its activities in accordance with the determination of the following regulatory instruments: Resolution No. 466/2012; Resolution 370/2007*(17)*; Resolution No. 240/1997*(18)*; Resolution No. 510/2016*(12)*; and Operational Standard no. 001/2013*(19)* of the National Health Council and the Ministry of Health (CNS/MS), the last CEP/FIMCA re-accreditation with CONEP took place in 2019, being identified in the Plataforma Brasil as CEP-12*(16)*.

The Aparício Carvalho University Center is in the city of Porto Velho, the capital of the state of Rondônia. This state consists of 52 municipalities with geo-economic, social, and cultural influence in other states in the North Region and neighboring countries. The university center has its own headquarters with 100,000 square meters and additional campus structures in two other cities in the state. It boasts modern physical facilities, laboratories, a simulation hospital, a rural campus, a veterinary hospital, and various other laboratories, as well as central classrooms, an amphitheater, and administrative facilities that comply with accessibility and safety regulations.

The university center offers undergraduate courses, such as medicine, biomedicine, nursing, pharmacy, physiotherapy, psychology, and others. Students in these courses could carry out research at one of the institutional research programs where humans participate as subjects. They could conduct subprojects as part of projects that receive funding through the Institutional Scientific Initiation Scholarship Program (PIBIC), while others receive funding from industry or scientific sup-

port foundations. The results obtained in many of these subprojects are used by the students to produce their undergraduate thesis (TCC), which could be substituted by a scientific paper.

As part of the national research system aimed at upholding bioethical principles, the CEP-12 maintains institutional relationships with the National Commission for Ethics in Research (CONEP/CNS/MS). This commission functions in accordance with established resolutions and operates in a collegial manner, sharing similar responsibilities with CEPs and serving as a link between all research ethics committees established throughout the Brazilian territory.

Based on the semi-annual reports of CEP-12 from 2018 to 2022, it was observed that the Committee was composed of 17 members during this period. The members represented diverse academic backgrounds and included both genders, with a representative of research participants appointed by the State Health Council or another relevant institution of society. Administrative support was provided by a secretary who attended to the initial demands of the CEP, along with its coordinators. Committee members were elected for a three-year term with the possibility of one reappointment, and participation in the committee was voluntary.

In terms of Committee meetings, according to reports submitted to CONEP, they are conducted in a dedicated room accessible only to members and the CEP secretary. At the start of each meeting, the quorum for deliberation on research protocols is verified, requiring at least fifty percent plus one of the members to be present. Following this, the meeting begins with information updates, and other issues such as requests from the internal research community and CONEP are discussed before the actual analysis of research protocols takes place.

After the initial updates and discussions, the coordinator of the Research Ethics Committee begins the analysis and designates a member to act as the rapporteur for a specific research protocol. The rapporteur presents their ethical analysis, often by reading their report, and this report is then discussed by the rest of the committee. After thorough deliberation, the committee provides its opinion, which is then sent to the coordinator for a final decision and the formatting of the report that will be sent to the researcher who submitted the research project.

During the analyzed period, there was a noticeable decline in the number of research protocols submitted to CEP 12 for review of the methods involving human subjects by the rapporteurs, particularly between 2020 and 2022. This can be attributed in part to the restrictive measures resulting from the COVID-19 pandemic. As a result of the pandemic, several research facilities, laboratories, and other resources were closed, preventing their use for research not only in biomedical sciences but also in the human and applied social sciences.

From 2018 to 2022, CEP-12 reviewed a total of 865 research protocols, as shown in Figure 2. These protocols had various purposes, including scientific initiation subprojects, undergraduate and specialization, and master's thesis. According to Batista and cols*(19)*, any research that involves human beings, regardless of the level of the study, such as undergraduate course completion work, scientific initiation projects, or any other research of academic or operational interest, must be submitted to CEP for review.

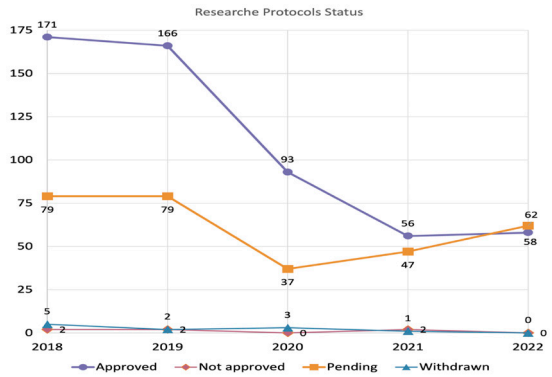


Figure 2 - Research methods approved, not approved, withdrawn, and archived by CEP-12 (2018 to 2022).

The number of research protocols reviewed over the five-year period reflects the strong research performance of the institution and the vital deliberative and educational role played by CEP-12.

These protocols reviewed belong to different science fields, such as biomedical (70%), humanities (20%), and applied social sciences (10%). The committee has demonstrated its ability to respond quickly to researchers while ensuring that the ethicality of the analyzed projects is upheld. The guidance provided in the resulting opinions has an educational character that contributes to the ethical quality of scientific research developed at the Institute and to the protection of study participants.

The preservation of Amazonian biodiversity is of particular concern, especially regarding the ancestral knowledge of traditional populations and how to safeguard it in the face of outsiders entering these communities and appropriating their knowledge, according to reports. It's worth noting that Ethics Committees do not propose regulations, but rather respond to the demands of researchers. The Ethics Committee at CEP-12 shares this concern, particularly when reviewing projects that involve these populations.

Health courses, particularly Medicine, Biomedicine, and Nursing, have highlighted several issues, such as the study of serological markers of hepatitis B and C, Hansen's disease distribution in Porto Velho-RO, epidemiological and operational aspects in individuals aged 18 to 60 (2014-2020), and the prevalence of human infection by the new coronavirus (Sars-CoV-2) in a neighborhood in Porto Velho/RO, among others. In each institution, Ethics Committees serve as the reference for ethical and bioethical development in projects that involve human beings.

Final considerations

The Research Ethics Committee with human subjects - CEP 12 operates according to the Resolutions and operational norms of the National Health Council/CONEP and its own internal regulations, with the objective of safeguarding the dignity of research participants. The CEP serves as a form of social control, acting as an intermediary between the researcher and the participants involved in the research. It guides researchers on the necessary precautions to take with the collected materials, while ensuring the confidentiality of research reports and notifications*(20)*.

During the pandemic period, CEP 12 conducted its activities in compliance with circular letter no. 07/2020-CONEP/SECNS/ME*(21)*, with virtual and remote meetings taking place every two weeks. The Committee took all necessary precautions to ensure the research projects' confidentiality and ethical review. The flow of activities occurred through the Brazil Platform System, which received, verified, and distributed the projects to the rapporteurs for review. To ensure the continuity of research, remote activity was also implemented. On the committee meeting day, members held a videoconference on the Meet platform from a private space in their homes. The CEP coordination directed the work, with each rapporteur presenting their opinion, and the committee expressed their vote through a plenary session once the minimum number of attendees was established.

The number of projects submitted to the Ethics Committee highlights the contributions of medical science studies towards scientific advancements, through research results, clinical findings, and feedback to research participants and the scientific community.

References

1. Ab'Saber AN. Bases para o estudo dos ecossistemas da Amazônia brasileira. *Estudos Avançados* 2002; 16(45): 7-30.
2. Souza NS. A Amazônia brasileira: processo de ocupação e a devastação da floresta. *Boletim Científico Escola Superior do Ministério Público da União* 2010; (32/33): 199-235.
3. DeGeer ME. Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge. *New Eng. J. Int'l & Comp. L.* 2003; 9: 179.
4. Barbosa AS, Oliveira-Boery RNS, Boery EN, Gomes-Filho DL, da Silva Sena EL, da Silva-Oliveira AA. (2011). A Resolução 196/96 e o sistema brasileiro de revisão ética de pesquisas envolvendo seres humanos. *Revista Bioética 2011*; 19(2): 523-542.

5. Conselho Nacional de Saúde (Brazil). Resolução Nº 196, de 10 de outubro de 1996. Diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. *Diário Oficial da União* 16 Oct 1996; Section 1 [access Jan 17, 2021]. https://bvsms.saude.gov.br/bvs/saudelegis/cns/1996/res0196_10_10_1996.html
6. Costa MOC, Ramos PIP, Guimarães IN, Moreira LMA. Comitês de ética em pesquisa no Brasil. *Revista de Ciências Médicas e Biológicas* 2009; 8(2): 182-188.
7. Ministério da Saúde (Brazil) [homepage on the internet]. *Plataforma Brasil* [access Apr 10, 2021]. https://plataformabrasil.saude.gov.br/visao/publico/indexPublico.jsf
8. Comissão Nacional de Ética em Pesquisa (Brazil). *Boletim CONEP* 2018 [access Apr 10, 2021]. http://www.conselho.saude.gov.br/Web_comissoes/conep/aquivos/be_12-2018.pdf
9. Conselho Nacional de Saúde [homepage on the internet]. *Comissão Nacional de Ética em Pesquisa* [access Apr 08, 2021]. https://conselho.saude.gov.br/comissoes-cns/conep
10. Conselho Nacional de Saúde [homepage on the internet]. *Conselhos de Ética em Pesquisa* [access Sep, 01 2022]. http://conselho.saude.gov.br/comites-de-etica-em-pesquisa-conep?view=default
11. Conselho Nacional de Saúde (Brazil). Resolução Nº 466, de 12 de dezembro de 2012. Diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. *Diário Oficial da União* 13 jun 2012; Section 1 [access Sep 10, 2022]. https://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf
12. Conselho Nacional de Saúde (Brazil). Resolução No. 510, de 7 de abril de 2016. Normas aplicáveis a pesquisas em Ciências Humanas e Sociais cujos procedimentos metodológicos envolvam a utilização de dados diretamente obtidos com os participantes ou de informações identificáveis ou que possam acarretar riscos maiores do que os existentes na vida cotidiana. *Diário Oficial da União* 24 maio 2016; Seção 1:44-46 [access Oct 20, 2022]. https://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf
13. Conselho Nacional de Saúde (Brazil). *Manual operacional para comitês de ética em pesquisa*. Brasília, DF: Ministério da Saúde, 2002 [access Sep 16, 2022]. https://conselho.saude.gov.br/biblioteca/livros/Manual_Operacional_miolo.pdf .
14. Conselho Nacional de Saúde (Brazil). Resolução Nº 1, de 13 junho de 1988. Estabelece aspectos éticos em pesquisa em seres humanos. Revoga a portaria 16 de 27.11.81, da Divisão Nacional de Vigilância Sanitária de Medicamentos que instituiu o termo de consentimento de risco (TCR). *Diário Oficial da União* 14 junho 1988; Seção 1 [access Sep 16, 2022]. https://conselho.saude.gov.br/resolucoes/reso_88.htm#:~:text=SITUA%C3%87%C3%83O-,01,-13/06/1988
15. Hossne WS. Desafio e perspectiva da ética em pesquisa. Rio de Janeiro, 2005 [access Mar 22, 2021]. http://www.ghente.org/etica/artigos_conep.html
16. Comitê de Ética em Pesquisa com Seres Humanos. *Regimento Interno*. Porto Velho, RO: Centro Universitário Aparício Carvalho; 2022.
17. Conselho Nacional de Saúde (Brazil). Resolução No. 370, de 08 março de 2007. O registro e credenciamento ou renovação de registro e credenciamento do CEP. *Diário Oficial da União* 4 abril 2007; Seção 1 [access Apr 10, 2021]. https://bvsms.saude.gov.br/bvs/saudelegis/cns/2007/res0370_08_03_2007.html
18. Conselho Nacional de Saúde (Brazil). Resolução No. 240, de 05 junho de 1997. *Sobre a definição do termo "usuários" para efeito de participação nos Comitês de Ética em Pesquisa das instituições* [access 10 Apr 10, 2021]. https://bvsms.saude.gov.br/bvs/saudelegis/cns/1997/res0240_05_06_1997.html
19. Conselho Nacional de Saúde (Brazil). Norma Operacional Nº 001 de 30 de Set de 2013. *Dispõe sobre a organização e funcionamento do Sistema CEP/CONEP, e sobre os procedimentos para submissão, avaliação e acompanhamento da pesquisa e de desenvolvimento envolvendo seres humanos no Brasil, nos termos do item 5, do Capítulo XIII, da Resolução CNS n° 466 de 12 de dezembro de 2012* [access 20 Mar 20, 2021]. http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Norma_Operacional_n_001-2013_Procedimento_Submisso_de_Projeto.pdf
20. Batista KT, Andrade RR, Bezerra NL. The role of Research Ethics Committees. *Revista Brasileira Cirurgia Plástica* 2012; 27(1): 150-155.
21. Conselho Nacional de Saúde (Brazil). Carta Circular nº7/2020 CONEP/SECNS/ME de 16 de mar de 2020. *Autorização, em caráter excepcional, para a realização de reuniões por meio de videoconferência ou aplicativo web de videochamada* [access Apr 10, 2021]. https://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/Carta_Circular_7_2020.pdf

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