Acta Bioethica 2024; 30(1): 67-77. http://dx.doi.org/10.4067/S1726-569X2024000100067

A PERSPECTIVE ON RESEARCH ETHICS COMMITTEES IN THE BRAZILIAN AMAZON

Aparício Carvalho de Moraes[1], Rui Nunes[2]

Abstract: This study presents the importance of the Research Ethics Committees (CEP) in the context of the Brazilian North Region, formed by the Amazon rainforest, which is occupied by traditional populations and those constituted by migratory currents. This study aims to analyze the bioethical implications arising from the activities of CEPs in the ethical evaluation of research projects and their essential role in protecting vulnerable populations. The authors seek to highlight the importance of ethics committees in the Amazon and their importance face the modern bioethical values that can contribute to the preservation of one of the most valuable and diverse environments on earth.

Keywords: Amazon region, bioethics, vulnerable populations, informed consent, National Research Ethics Commission

Una perspectiva sobre los comités de ética de la investigación en la amazonia brasileña

Resumen: Este estudio presenta la importancia de los comités de ética en investigación (CEP) en el contexto de la Región Norte de Brasil, formada por la selva amazónica, ocupada por poblaciones tradicionales y constituida por corrientes migratorias. Este estudio tiene como objetivo analizar las implicaciones bioéticas derivadas de las actividades de los CEP en la evaluación ética de los proyectos de investigación y su papel esencial en la protección de las poblaciones vulnerables. Los autores buscan destacar la importancia de los comités de ética en la Amazonia y su importancia frente a los valores bioéticos modernos que pueden contribuir a la preservación de uno de los ambientes más valiosos y diversos del planeta.

Palabras clave: región amazónica, bioética, poblaciones vulnerables, consentimiento informado, Comisión Nacional de Ética en Investigación

Uma Perspectiva sobre Comitês de Ética em Pesquisa na Amazonia Brasileira

Resumo: Esse estudo apresenta a importância dos Comitês de Ética em Pesquisa (CEPs) no contexto da Região Norte Brasileira, formada pela floresta amazônica e ocupada por populações tradicionais e aquelas constituídas por correntes migratórias. Esse estudo objetiva analisar as implicações bioéticas que surgem das atividades dos CEPs na avaliação ética de projetos de pesquisa e seu papel fundamental em proteger populações vulneráveis. Os autores procuram enfatizar a importância dos comitês de ética na Amazônia e sua importância face a valores bioéticos modernos, que podem contribuir para a preservação de um dos mais valiosos e diversos ambientes na terra.

Palavras-chave: região amazônica, bioética, populações vulneráveis, consentimento informado, Comissão Nacional de Ética em Pesquisa

---

[1] Faculty of Medicine of the University of Porto, Portugal, aparicio.moraes@uol.com.br

[2] University of Porto, Portugal, https://orcid.org/0000-0002-1377-9899

Introduction

The Amazon region holds a remarkable status as a unique ecosystem. This biome spans nine countries, covering an area of 6.7 million km2, harboring at least 10% of the world's known biodiversity*(1)*, along with 17% of the world's freshwater*(2)*. The tropical forest in South America serves as the habitat for a staggering 1.8 million species of plants, animals, and microorganisms*(3)*. Within Brazil's Amazon region alone, approximately 180 indigenous peoples reside, comprising a population of around 208,000 individuals, including various isolated groups*(4)*.

During the mid-20th century, the negative impacts caused by colonization processes in the Amazon intensified, leading to a second wave of displacement among indigenous peoples. This had severe consequences for their living conditions, exacerbating the historical context of dispossession and vulnerability. The most recent cycle involves the appropriation of traditional knowledge, its associated diversity, and genetic resources*(5)*. This new facet of the extensive historical expropriation process is readily observable through patent data that reflects the utilization of traditional knowledge linked to the biodiversity of the Amazon, highlighting the expropriation through industrial property*(6)*.

The implementation of Ethics Committees in research institutions located in the Amazon region plays a vital role in safeguarding traditional communities from potential harm and losses arising from their involvement in research and technological development activities. This marks a significant historical turning point.

The objective of this study is to present a discussion on the role of Ethics Committees (CEP) in the Northern Region of Brazil, which encompasses the Brazilian Amazon, the region that represents the majority of the Amazon area, and the vast potential of traditional knowledge found within its biodiversity and local populations. Given the expansive and diverse nature of this territory, the importance of Ethics Committees as oversight and protective bodies for research subjects, their knowledge, and consequently, the existing heritage, is thoroughly examined. Additionally, as a positive externality, a secondary aim is to assess whether promoting ethics and integrity in science in the Amazon region will contribute to the improved well-being of the environment and biodiversity.

Research and ethical regulation in Brazil

Ethics is rooted in the Greek ideal of fair measure and balanced actions, enabling the establishment of judgments that establish guidelines and norms for human conduct, ultimately benefiting all parties involved*(7)*. As a result, ethical values have a significant impact on the activities of all professions, especially those in the healthcare field, particularly in the context of research involving human subjects. In such research, ethics, and autonomy play a crucial role in maintaining a delicate connection between the researcher and the research participants*(8)*.

It is important to highlight the necessity of separating research regulation from healthcare regulation within the responsibilities of these professionals. This separation aims to protect individuals enrolled in research while ensuring that the investigation does not harm any of the involved parties*(9)*. The participant or subject of the research should always be the focal point as they are the most vulnerable part of the research relationship. Often, they are the custodians of the information present in their medical records, and it is the responsibility of professionals to ensure their voluntary participation, access to data, and publication*(10)*.

When it comes to research ethics, it can be argued that their significance heightened after World War II, when the Nuremberg Trials revealed the atrocities committed against human beings in the name of science and the greater good. Twenty-three individuals, including twenty doctors, were prosecuted as war criminals and for crimes against humanity due to the horrific experiments conducted on humans*(11)*.

The investigation and exposure of these events compelled scientific and political authorities to respond decisively, ensuring that such incidents would never recur. This led to the development and adoption of the Nuremberg Code in 1947, which can be considered a pivotal moment in human history. It established, for the first time, a set of ethical guidelines with international implications for human research*(11)*. Today, all types of research involving human subjects, including epidemiological studies, are regulated*(12)*.

Furthermore, the international community recognized the need for universal ethical norms. For instance, UNESCO approved the Universal Declaration on Bioethics and Human Rights*13)* to promote the global implementation of fundamental values. Unfortunately, despite the endorsement of various declarations and conventions, ethical lapses have persisted, necessitating the establishment of enforceable national standards to prevent such infractions*(14)*.

The awareness of these events had a profound global impact, including in Brazil, resulting in the strengthening of ethical codes of conduct in research and the emergence of regulatory bodies to safeguard basic human rights*(15)*. In Brazil, the field of bioethics emerged relatively late, with organic development occurring in the 1990s*(16)*. It was later incorporated into legislation through Resolution No. 196/1996*(17)* issued by the National Health Council (CNS) of Brazil, which operates under the Ministry of Health and was established by Law No. 8080 on September 19, 1990*(18)*, the Research Ethics Committee (CEP) and the National Research Ethics Commission (CONEP) were institutionalized. These entities are responsible for regulating and overseeing human research across the entire national territory, which includes 27 states and the Federal District.

With the establishment of CONEP, human research in Brazil became subject to stricter regulation. Presently, there are over 864 Research Ethics Committees, including those affiliated with hospitals, universities, and research institutes, which convene regularly. These committees comprise a total of 2,388 coordinators, 10,149 reporting members, 943 research participant representatives, 905 secretaries, and 54 advisors, amounting to a collective effort of 14,077 collaborators*(19)*.

As a result, Resolution No. 196/1996*(17)* has taken the lead in incorporating ethical considerations for research projects involving human subjects, directly or indirectly, across all research institutions in Brazil. The Research Ethics Committees (CEPs) serve as a convenient channel for both researchers and study participants. Institutions seeking to become part of the system must apply for accreditation from CONEP, the governing authority of the system, and ensure the functioning of their CEPs*(19)*.

The establishment of a CEP necessitates careful formulation and the involvement of multidisciplinary expertise to ensure a comprehensive evaluation of all aspects of the institution's proposed research. Ethical considerations must be considered in all research involving human subjects, whether directly or indirectly. In addition to reviewing research protocols, Research Ethics Committees have a deliberative, consultative, and educational role in fostering ethical discourse in scientific research, starting from project conception through the final report and publication*(20)*.

It is important to highlight that the CEP is composed of a minimum of seven full members selected from various fields, including health, exact sciences, social sciences, humanities, and civil society. A quorum of 50 percent plus one is required for CEP deliberations. The number of members needed to fulfill its functions depends on the total number of full members, and decisions are made based on a simple majority vote of those present*(21)*.

CEPs have the ability to engage ad hoc consultants to assist in the examination of specific research procedures, although the final decision rests with the committee itself. The participation of community members, referred to as “user representatives,” is crucial in ensuring that the decision-making process remains independent from external influence by the research institution*(22)*.

The role of CONEP and CEPs in the education and supervision of research endeavors ensures the protection of the fundamental rights of all members of society*(18)*. It is important to note that the existence of a CEP does not guarantee the fulfillment of ethical research norms. Evaluation criteria and operational capacity are vital components of the system. The CEP/CONEP system has gone through several phases before evolving into a national platform. The National Information System on Research Ethics Involving Human Beings (SISNEP) was one of the initial initiatives aimed at establishing a national research database for studies involving human subjects*(23)*. However, in the present era of global digital transformation, special safeguards must be implemented concerning big data*(24,25)* and artificial intelligence*(26)* in research.

In Brazil, efforts are being made to enhance the efficiency and effectiveness of these committees. Initially, research projects were presented in person, followed by a transition to CD-based electronic submissions, which resulted in varying approaches by researchers and delays in obtaining opinions*(27)*.

With the rapid growth of research projects and the implementation of the National Health Council's Resolution No. 466/2012*(22)*, a new methodological framework for analyzing human-centered research initiatives emerged, accelerating the need for the implementation of the Plataforma Brasil. Through this platform, projects are submitted to the committees via an internet portal designed specifically for this purpose*(28)*. Undoubtedly, in Brazil as well as in other countries, new information and communication technologies are profoundly transforming the conduct and regulation of science, as well as healthcare, in terms of speed, reach, and interconnectedness*(29,30)*.

Indeed, CEP members and other researchers must register on the nationwide and unified database of research records involving human beings called Plataforma Brasil. They submit their projects through this platform, where the examination of documents, reporting, and subsequent committee evaluations take place. The Plataforma Brasil enables the monitoring of research at various stages, from submission to approval by the CEP and, if necessary, CONEP, as well as facilitating field follow-up and the submission of interim and final reports*(30)*.

Resolution No. 466/2012*(22)* sparked discussions and led to the drafting of Resolution No. 510/2016*(31)*, which specifically focuses on projects in the humanities and social sciences. Researchers must choose one of these two resolutions based on the subject of their study.

Once the projects are submitted to the CEP, the administrative secretariat registers them and conducts a checklist to ensure all necessary documents are included. A member/reporter is then assigned to the project, receiving a notification regarding any concerns raised by the platform. The reporter analyzes the project and provides their own assessment before the projects are deliberated upon in a plenary session by the other committee members. These plenary sessions occur on a monthly or fortnightly basis, depending on the number of projects to be evaluated after the rapporteur completes their report.

It is important to note that according to Resolution No. 466/2012*(22)* guidelines, all research endeavors across various scientific disciplines, including but not limited to humanities, social sciences, exact sciences, and biomedical fields, that involve human participants, either directly or indirectly, must undergo review by Research Ethics Committees (CEPs). This requirement applies to a wide range of projects, such as undergraduate dissertations, specialized courses, and postgraduate programs like master's and Ph.D. studies. The role of the committee is to regulate and supervise research activities, ensuring that the implementation of the projects upholds the dignity and fundamental rights of the study participants*(17)*.

Ethics committees in the amazon region

The Amazon region is globally recognized for its rich biodiversity and the presence of indigenous populations, who possess a unique cultural heritage*(32)*. Given the importance of biodiversity in the Amazon, bioethics plays a crucial role as a catalyst for social transformation. Ethical considerations, particularly in studies involving human subjects, are of utmost importance, encompassing aspects such as the treatment of individuals, the potential risks associated with research, and the benefits that research outcomes may bring*(33)*. Bioethics assumes significant significance in research, especially in the Amazon region, due to the intricate interplay between local communities, indigenous peoples, and biodiversity. It necessitates a contextual framework of informed consent (both individual and collective), respect for the diverse cultural fabric of the local community, and an emphasis on social and cultural components that foster a culture of care*(34).*

The issue of raising awareness among local populations has become critical, particularly considering the persistent practice of biopiracy, which entails illegal actions with numerous detrimental consequences for the region. Such practices violate ethical standards and result in the removal of local species from their natural habitat, even from the country itself*(35).* Unfortunately, there is limited information available on this illicit phenomenon, and whatever data exists is primarily found in law enforcement agencies, where such behavior is sometimes tolerated. This underscores the importance of ethics education, a specific responsibility of ethics committees. Collaborating with local populations to convey the value of wildlife, plant life, and human beings, as well as the adverse societal effects of biopiracy, is considered a constructive and impactful endeavor*(36).*

One crucial aspect to address in research involving human subjects, particularly in the Amazon Region, is informed consent. Similar to other regions, any research project being conducted must thoroughly analyze the ethical considerations concerning human participants. This includes criteria for participant selection, assessment of benefits and risks, methodology for data collection and analysis, and other relevant factors, once the study's objective and the governing resolution have been defined. Several documents are required to be included in the research, such as the Free and Informed Consent Form (FICF), the Permission Form from the study site, and, in certain situations, the Assent Form, along with copies of data collection instruments. In Brazil, the FICF, established by Resolution No. 466/2012*(22)* as the TCLR, serves as the document in which the researcher provides comprehensive information about the research, including risks, benefits, objectives, and feedback, among other details. This document establishes a connection between the researcher and the research participants that must reflect an ethical stance and respect for the most vulnerable party, which is the participating subject*(37,38)*. Obtaining informed consent can present challenges in ensuring participants are fully informed, particularly among individuals with limited health literacy. This is particularly relevant for high-vulnerable populations, including underrepresented minorities such as indigenous peoples, quilombolas, and other traditional communities of the Amazon rainforest*(39),* where effective implementation of the consent process becomes even more critical*(40).*

Informed consent must be obtained freely and voluntarily from the subjects*(41,42).* This means that individuals participating in the research must have the legal capacity to provide consent. They should be able to make their own decisions without being subjected to force, deception, coercion, manipulation, or any other form of undue influence. They must have a sufficient understanding of the study in question to make an informed decision. This includes explaining the nature, duration, and purpose of the experiment, the methods of its execution, the potential inconveniences and risks involved, and the possible effects on the participants' health. The researcher who initiates, oversees, or engages in the experiment bears the responsibility to ensure the quality of the consent process. These obligations and duties are personal and cannot be delegated to others without consequences*(43).*

This is particularly relevant in the Amazon Region due to two distinct factors. First, vulnerable populations are often included in research projects, requiring special precautions to ensure their protection. Individual consent is necessary, but it is not sufficient. It is crucial to establish transparency and rationality between the objectives of the study and the inclusion of vulnerable populations*(44).*

Secondly, effectively conveying the objectives and potential impacts of a research project to participants from vulnerable populations within their specific cultural contexts presents challenges. Obtaining informed consent from these communities is imperative. This requires allocating resources and dedicating time to engage in discussions with local representatives of the vulnerable population, ensuring the full protection of their rights*(45).*

In terms of the regulatory context in the Brazilian North Region, which includes the Amazon, the legal framework for analyzing and monitoring research involving human subjects is currently being developed. The North Region comprises 72 Research Ethics Committees, as reported by the CONEP National Research Commission in 2021 (Figure 1). We analyzed the distribution and number of these committees across the states of the North Region, which are listed in Table 1.

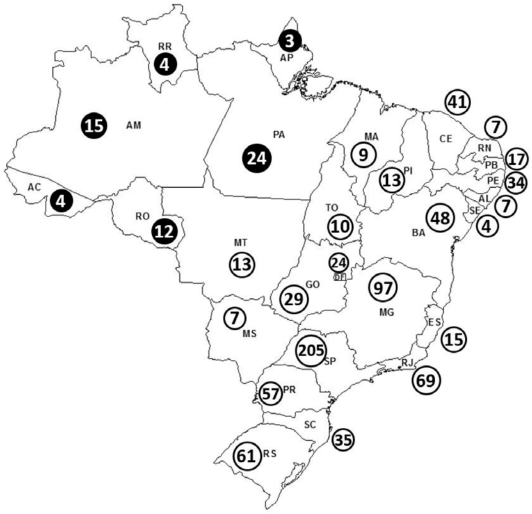

Figure 1: Distribution of Research Ethics Committees (CEPs) by Member-State in Brazil. The northern states are represented by dark circles. Source: National Research Commission, 2021*(46)*.

To gain a better understanding of the presence and distribution of Ethics Committees, a survey was conducted to identify the formal classification of the institutions in which they operate, as shown in Table 2. The findings revealed that the majority (52 of them) are affiliated with higher education institutions, while the remaining committees (28 of them) are associated with private organizations.

Table 2. Quantitative breakdown of Research Ethics Committees in the North Region, categorized by institution type*(46)*.

Institutional Linkage of CEPs in the North Region	Number of CEPs
Private University	28
Public University	24
Hospital	10
Research Center	8
State Department of Health	2
TOTAL	72

This implies that higher education institutions in the North Region are expanding their activities beyond teaching to include research involving human subjects. Numerous studies conducted within their postgraduate programs focus on ethnographic and comparative research of traditional indigenous and non-indigenous populations, cultures, traditional knowledge, and religious practices related to biodiversity and agrobiodiversity. These studies explore various aspects, such as ways of life, social organization, kinship, cosmology, rituals, indigenous theories, society-nature relationships, and classification systems*(47)*.

Research conducted with vulnerable traditional indigenous and non-indigenous populations in the Amazon Region requires careful attention and safeguards. This includes protecting against biopiracy, recognizing, and preserving the knowledge held by local communities, and ensuring their participation in the economic benefits derived from their knowledge of biodiversity*(48)*.

Conclusions

Ethics committees in human research play a crucial role in ensuring social control and regulation, aiming to treat research participants with respect, in line with universal ethical principles and fundamental human rights. It is essential that these committees operate independently and remain free from external interference, including hierarchical superiors, market forces, or any other external stakeholders, to uphold researchers' independence, integrity, and unbiased conclusions.

This prevents them from being influenced or manipulated for the benefit of any specific research project stakeholder. The primary objective of ethics committees is to ensure the adherence to ethical principles in research and the protection of participants' rights under all circumstances.

The survey conducted in the North Region identified 72 Research Ethics Committees that meet the legal criteria and have regular status with CONEP (National Research Commission) and Plataforma Brasil registration. This region exhibits an innovative architecture of ethics committees, distributed across different states. Although ethics committees are a relatively recent practice in Brazil, their institutionalization began in the 1990s as a significant milestone in the ethical review of research involving human subjects, ensuring the preservation of human dignity.

Consequently, as the number of ethics committees continues to grow. The formal existence and ongoing activities of these committees should be acknowledged by the international community as a sign that bioethical principles are applied in studies involving minorities, such as traditional communities, in accordance with the latest principles of participant protection in research, through the ethical assessment of all research involving direct or indirect participation of human beings.

Table 1: Research Ethics Committees (CEPs) registered at the National Research Commission (CONEP) in 2021*(46).*

State	Total	**Committees**
Acre (AC)	4	1. Centro Universitário Meta - UNIMETA
		2. Hospital das Clínicas do Acre - HCA/FUNDHACRE
		3. Universidade Federal do Acre - UFAC
		4. União Educacional do Norte - UNINORTE
Amazonas (AM)	15	1. Centro Universitário do Norte - UNINORTE
		2. Centro Universitário Luterano de Manau - CEULM/ULBRA
		3. Centro Universitário Nilton Lins - UNINILTONLINS
		4. Faculdade Estácio do Amazonas - ESTÁCIO AMAZONAS
		5. Fundação Alfredo da Matta - FUAM
		6. Fundação Centro de Controle de Oncologia do Amazonas - FCECON
		7. Fundação de Hematologia e Hemoterapia do Amazonas - HEMOAM
		8. Fundação de Medicina Tropical Doutor Heitor Vieira Dourado - FMT-HVD
		9. Fundação Hospital Adriano Jorge - FHAJ
		10. Hospital Universitário Getúlio Vargas - UFAM
		11. Instituto de Desenvolvimento Sustentável Mamirauá - IDSM
		12. Instituto Federal de Educação, Ciência e Tecnologia do Amazonas - IFAM
		13. Instituto Nacional de Pesquisas da Amazônia - INPA/MCT
		14. Universidade do Estado do Amazonas - UEA
		15. Universidade Federal do Amazonas - UFAM

Amapá (AP)	3	1. Instituto de Pesquisas Científicas e Tecnológicas do Estado Amapá - IEPA
		2. Faculdade Estácio de Macapá - Estácio Macapá
		3. Universidade Federal do Amapá - UNIFAP
Pará (PA)	24	1. Centro de Ciências Biológicas e da Saúde da Universidade Estadual do Pará - UEPA
		2. Centro de Saúde Escola do Marco Teodorico da Universidade Estadual do Pará - CESEM/UEPA
		3. Centro Universitário do Pará - CESUPA
		4. Curso de Educação Física - UEPA
		5. Faculdade de Ensino Superior da Amazônia Reunida - FESAR
		6. Faculdade Integrada Brasil da Amazônia - FIBRA
		7. Faculdade Metropolitana da Amazônia - FAMAZ
		8. Fundação Pública Estadual Hospital das Clínicas Gaspar Vianna - FHCGV
		9. Fundação Santa Casa de Misericórdia do Pará - FSCMPA
		10. Hospital Ophir Loyola - HOL
		11. Hospital Regional do Baixo Amazonas do Pará Dr. Waldemar Penna - HRBA
		12. Hospital Universitário João de Barros Barreto da Universidade Federal do Pará - UFPA
		13. Instituto Campinense de Ensino Superior - ICES-UNAMA
		14. Instituto de Ciências da Saúde da Universidade Federal do Pará - UFPA
		15. Instituto Evandro Chagas - IEC/SVS/MS
		16. Museu Paraense Emílio Goeldi - MPEG/MCTIC
		17. Núcleo de Medicina Tropical - NMT/UFPA
		18. Núcleo de Pesquisa em Oncologia da Universidade Federal do Pará - UFPA
		19. Universidade do Estado do Pará - Núcleo de Formação Indígena - UEPA
		20. Universidade do Estado do Pará - UEPA
		21. Universidade do Estado do Pará - Centro de Ciências Biológicas e da Saúde - UEPA
		22. Universidade do Estado do Pará - Curso de Graduação em Enfermagem - UEPA
		23. Universidade Estadual do Pará Campus VIII - UEPA
		24. Universidade Federal do Oeste do Pará - UFOPA

Rondônia (RO)	12	1. Centro Universitário Aparício Carvalho – FIMCA
		2. Centro Universitário São Lucas - UNISL
		3. Centro Universitário São Lucas Ji-Paraná - UNISL
		4. Centro de Pesquisa em Medicina Tropical - CEPEM - Rondônia
		5. Faculdade de Ciências Biomédicas de Cacoal - FACIMED
		6. Faculdade de Educação e Cultura de Vilhena - FAEV/UNESC
		7. Faculdade de Educação e Meio Ambiente - FAEMA
		8. Faculdade de Rondônia - FARO
		9. Instituto Federal de Educação, Ciência e Tecnologia de Rondônia - IFRO
		10. Sociedade Rolimourense de Educação e Cultura - FAROL
		11. Universidade Federal de Rondônia - UNIR
		12. União das Escolas Superiores de Ji-Paraná - UNIJIPA
Roraima (RR)	4	1. Faculdade Cathedral de Ensino Superior - FACES/RR
		2. Faculdade Roraimense de Ensino Superior - FARES/RR
		3. Universidade Estadual de Roraima - UERR
		4. Universidade Federal de Roraima - UFRR
Tocantins (TO)	10	1. Centro Universitário Luterano de Palmas - ULBRA
		2. Centro Universitário Tocantinense Presidente Antônio Carlos - UNITPAC
		3. Faculdade de Ciências de Tocantins - FACIT
		4. Fundação Escola de Saúde Pública de Palmas - FESP
		5. Fundação Universidade Federal do Tocantins - UFT
		6. Hospital de Doenças Tropicais da Universidade Federal de Tocantins - UFT
		7. Instituto Federal de Educação, Ciência e Tecnologia do Tocantins - IFTO
		8. Instituto Tocantinense Presidente Antônio Carlos Porto - ITPAC PORTO
		9. Universidade Estadual do Tocantins- UNITINS
		10. Universidade de Gurupi - UnirG
Total	72	CEPs in Northern Brazil region

References

1. Viana G. Impactos Ambientais da Política de Globalização da Amazônia. In: Viana G, Silva M, Diniz N. *O Desafio da Sustentabilidade: um debate socioambiental no Brasil*. São Paulo: Editora Fundação Perseu Abramo; 2001: 265-288.
2. Bezerra J. *The Brazilian Amazon: Politics, Science and International Relations in the History of the Forest*. Cham: Springer International Publishing; 2015.
3. Becker B, Stenner C. *Um Futuro para a Amazônia*. São Paulo: Oficina de Textos; 2008.
4. Heck E, Loebens F, Carvalho PD. Amazônia indígena: conquistas e desafios. *Estudos Avançados* 2005; 19(53): 237-255.
5. Comisión Económica para América Latina y el Caribe. *Los pueblos indígenas en América Latina: avances en el último decenio y retos pendientes para la garantía de sus derechos*. Santiago de Chile: Naciones Unidas; 2014.
6. Davies LF, Kessler MS. A apropriação ambiental no sistema de patentes biotecnológicas e a perspectiva de inclusão dos conhecimentos tradicionais como direito. *Revista Eletrônica Direito & Política* 2015; 10(1): 440-462.
7. Beauchamp T, Childress J. *Principles of biomedical ethics*. 7ª ed. New York: Oxford University Press; 2013.
8. Council for International Organizations of Medical Sciences. *International ethical guidelines for health-related research involving humans*. Geneva: World Health Organization; 2016.
9. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. *The Belmont Report: ethical principles and guidelines for the protection of human subjects of research*. Washington: Government Printing Office; 1978.
10. Bankowski Z, Bryant JH, Gallagher J. Ethics, Equity and the Renewal of Who's Health-for-All Strategy. In: *Proceedings of the XXIXth Cioms Conference*; 1997 Mar 12-14; Geneva, Switzerland: Geneva: World Health Organization; 1997. p. 107-115.
11. Palácios M, Rego S, Schramm FR. A regulamentação brasileira em ética em pesquisa envolvendo seres humanos. In: Machado RM, Carvalho DM, Black CK, Luiz RR, Werneck GL, editors. *Epidemiologia*. São Paulo, SP: Atheneu; 2002: 465-477.
12. Council for International Organizations of Medical Sciences. (2009). *International ethical guidelines for epidemiological studies*. Geneva: World Health Organization; 2009.
13. United Nations Educational, Scientific and Cultural Organization. *Universal declaration on bioethics and human rights*. Paris: Unesco; 2006.
14. World Medical Association. WMA Declaration of Helsinki – ethical principles for medical research involving human subjects. *Jama* 2013; 310(20): 2191-2194.
15. Nunes R, Brandão C, Rego G. Public accountability and sunshine healthcare regulation. *Health Care Analysis* 2011; 19(4): 352-364.
16. Garrafa, V. Radiografia Bioética de um País - Brasil. *Acta Bioethica* 2000; 6(1): 171-175.
17. Conselho Nacional de Saúde (Brazil). Resolução Nº 196, de 10 de Out 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
18. Presidência da República (1990). Lei No. 8.080, de 19 de Set de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. *Diário Oficial da União* 20 Sep 1990; Section 1 [access Feb 19, 2021]. http://www.planalto.gov.br/ccivil_03/leis/l8080.html
19. Ministério da Saúde (Brazil) [homepage on the internet]. Comissão Nacional de Ética em Pesquisa. [access Mar 15, 2021]. Available in: http://conselho.saude.gov.br/comissoes-cns/conep/
20. Bussu S, Lalani M, Pattison S, Marshall M. Engaging with care: ethical issues in Participatory Research. *Qualitative Research* 2021; 21(5): 667–685.
21. 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
22. 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
23. Conselho Nacional de Saúde (Brazil) [homepage on the internet]. *Sisnep em consulta* [access May 25, 2023]. https://conselho.saude.gov.br/ultimas_noticias/2007/sisnepemconsulta.html

24. European Union Agency for Fundamental Rights. *BigData: Discrimination in data-supported decision making*. Vienna: European Union; 2018.
25. Ienca M, Ferretti A, Hurst S, Puhan P, Lovis C, Vayena E. Considerations for ethics review of big data health research: A scoping review. *PloS One* 2018; 13: e0204937-e0204937.
26. Independent High-Level Expert Group on Artificial Intelligence set up by the. *Ethics guidelines for trustworthy AI*. Helsink: European Commission; 2019.
27. Batista KT, Andrade RRD, Bezerra NL. O papel dos comitês de ética em pesquisa. *Revista Brasileira de Cirurgia Plástica* 2012; 27: 150-155.
28. 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
29. Olayiwola JN. Magaña C. Clinical Transformation in Technology: A Fresh Change Management Approach for Primary Care. *Harvard Health Policy Review*. 2019 [access on Oct 25, 2022]. http://www.huhpr.org/volume-18-issue-1-2/2019/2/2/clinical-transformation-in-technology-a-fresh-change-management-approach-for-primary-care
30. Boman M, Kruse E. Supporting global health goals with information and communications technology. *Global Health Action* 2017; 10(3): 6-13.
31. 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; Section 1: 44-46 [access Oct 20, 2022]. https://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf
32. Diegues AC, Arruda RSV, Silva VCF, Figols FAB, Andrade D. *Os saberes tradicionais e a biodiversidade no Brasil*. Brasília: Ministério do Meio Ambiente; 2006.
33. Ab'Saber AN. *Amazônia: do discurso à práxis*. 2nd. São Paulo: Edusp; 2001.
34. Marques DJC. *Bioética e sociobiodiversidade: visões e práticas das lideranças indígenas do Amazonas*. Manaus. Thesis [Doutorado em Biotechnologia] - Universidade Federal do Amazonas; 2012.
35. Imran Y, Wijekoon N, Gonawala L, Chiang YC, De Silva KRD. Biopiracy: Abolish Corporate Hijacking of Indigenous Medicinal Entities. *The Scientific World Journal* 2021; 2021: 1-8.
36. Carvalho AA, Ferreira JR. Do presente ao futuro: meio ambiente no contexto bioético. *Revista Bioética* 2019; 27(2): 359–369.
37. Saunders CM, Baum M, Houghton J. Consent, research and the doctor patient relationship. In: Gillon R. *Principles of health care ethics*. London: John Wiley & Sons; 1994: 457-470.
38. Concone MHVB, Cerveny CMDO. Research and the (free and) informed consent. *Ciência & Saúde Coletiva* 2008; 13: 341-349.
39. Silva JMS, Pontes AN. Participation, representation, and representativeness of traditional peoples and communities in Eastern Amazon State Water Resources Councils. *Brazilian Journal of Environmental* 2022; 57(3): 505-515.
40. Mainous AG, Kelliher A, Warne D. Recruiting Indigenous patients into clinical trials: a circle of trust. *The Annals of Family Medicine* 2023; 21(1): 54-56.
41. Manti S, Licari A. How to obtain informed consent for research. *Breathe* 2018; 14(2): 145-152.
42. Beauchamp TL. Informed consent: its history, meaning, and present challenges. *Cambridge Quarterly of Healthcare Ethics* 2011; 20(4): 515-523.
43. Nuremberg Military Tribunals. Permissible medical experiments. In: *Trials of war criminal before the Nuremberg Military Tribunals under Control Council Law n. 10*. Washington: U.S. G.P.O; 1949: 181-184.
44. Axelsson P, Sköld P. Indigenous populations and vulnerability. Characterizing vulnerability in a Sami context. *Annales de démographie historique* 2006; 111(1): 115-132.
45. Gusman CR, Rodrigues DA, Villela WV. Trâmites éticos, ética e burocracia em uma experiência de pesquisa com população indígena. *Saúde e Sociedade* 2016; 25: 930-942.
46. Ministério da Saúde (Brazil) [homepage on the internet]. Plataforma Brasil [access Apr 10, 2021]. https://plataformabrasil.saude.gov.br/visao/publico/indexPublico.jsf
47. Universidade Federal do Amazonas. *UFAM Graduate Programs*. [access on May 24, 2023]. https://edoc.ufam.edu.br/bitstream/123456789/4039/1/Catálogo de Pós-Pós Graduação Ufam.pdf
48. Lopes SRM. *Povos e comunidades tradicionais da Amazônia Legal: análise das normas jurídicas de acesso aos territórios e aos bens ambientais*. Belém. Thesis [Doutorado em Direito] - Universidade Federal do Pará; 2009.

Received: 29 May 2023
Accepted: 1 August 2023