

Bioethical aspects of scientific production in medicine from Venezuela 2018–2022

Jesus Brito-Núñez¹, Paola Estephania Guerra Di Bonaventura¹, Yeisson Rivero-Moreno², Roxana Naimi Moreno-Brito¹, Wilman Alexander Maurera-Díaz¹, Yasmin Piña¹, Saiddys Daniela López-Lezama¹, Andrea García¹, Paola Klaretsky Losada Muñoz¹, Stephanie Daniela Molina-García³, Jesus Santiago Bautista-Garzon³

1. Universidad de Oriente, Bolívar, Venezuela. 2. Medical Center, New York, USA. 3. University of the Andes, Mérida, Venezuela.

Abstract

The approval of projects by an ethics committee, compliance with informed consent and methodological rigor guarantees the reliability of research results and ethical integrity. The objective was to analyze the bioethical aspects of scientific medical production in Venezuela in the Scopus and Web of Science platform considering the 2018–2022 period. A bibliometric analysis of original articles published on research produced in Venezuela was carried out based on approval by a research ethics committee, the origin of the ethics committee, and the declaration of informed consent. Descriptive statistics and association were applied. A total of 523 articles were included, it was found that 50.7% of publications did not declare approval of the project by an ethics committee, 71% were carried out on humans, 69.4% were published in international journals, 44% did not comply with informed consent, and publications from Caracas and Zulia had higher rates of approval by ethics committees.

Keywords: Ethics committees, research. Scientific publication ethics. Informed consent. Bioethics. Venezuela.

Resumo

Aspectos bioéticos da produção científica em medicina na Venezuela 2018–2022

A aprovação de projetos por um comitê de ética, o cumprimento do consentimento informado e o rigor metodológico garantem a confiabilidade dos resultados da pesquisa e a integridade ética. Este estudo objetivou analisar os aspectos bioéticos da produção científica médica na Venezuela nas plataformas Scopus e Web of Science, considerando o período de 2018 a 2022. Foi realizada uma análise bibliométrica de artigos originais publicados sobre pesquisas conduzidas na Venezuela, considerando a aprovação por comitê de ética em pesquisa, a origem do comitê e a declaração de consentimento informado. Foram aplicadas estatísticas descritivas e de associação. Um total de 523 artigos foram incluídos, e constatou-se que 50,7% das publicações não declararam a aprovação do projeto por um comitê de ética, 71% foram realizadas em seres humanos, 69,4% foram publicadas em periódicos internacionais, 44% não cumpriram com o consentimento informado, e as publicações de Caracas e Zulia apresentaram maiores taxas de aprovação por comitês de ética.

Palavras-chave: Comitês de ética em pesquisa. Ética na publicação científica. Consentimento informado. Bioética. Venezuela.

Resumen

Aspectos bioéticos de la producción científica médica en Venezuela 2018–2022

La aprobación de proyectos por un comité de ética, el cumplimiento del consentimiento informado y el rigor metodológico garantizan la confiabilidad de los resultados de la investigación y la integridad ética. Este estudio tuvo como objetivo analizar los aspectos bioéticos de la producción científica médica en Venezuela en las plataformas Scopus y Web of Science, considerando el período del 2018 al 2022. Se realizó un análisis bibliométrico de artículos originales publicados sobre investigaciones realizadas en Venezuela, considerando la aprobación por un comité de ética en investigación, el origen del comité y la declaración de consentimiento informado. Se aplicaron estadísticas descriptivas y de asociación. Se incluyeron un total de 523 artículos, y se encontró que el 50,7% de las publicaciones no declaró la aprobación del proyecto por un comité de ética, el 71% se realizó con seres humanos, el 69,4% se publicó en revistas internacionales, el 44% no cumplió con el consentimiento informado, y las publicaciones de Caracas y Zulia presentaron mayores tasas de aprobación por comitês de ética.

Palabras clave: Comitês de ética en investigación. Ética en la Publicación Científica. Consentimiento informado. Bioética. Venezuela.

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Since the Declaration of Helsinki in 1964, efforts have been made to protect the dignity and privacy of research participants. It is within this framework that requirements are established, such as the need for a complete protocol to be reviewed and approved by an ethics committee, as well as controlling and monitoring the research¹. These committees are also responsible for ensuring adequate conflict management starting from the design and planning stages and throughout the development and analysis of the study².

Until recently, terms such as medical ethics, bioethics, or ethics committee were unfamiliar in clinical medicine and experimental science. Technological and computing advances have changed this landscape, facilitating access to knowledge. An evolution in the physician-patient relationship stands out, changing from classic paternalism to being governed by patient autonomy and informed consent³.

This extends beyond human beings, also covering animals and plants, via the Cruelty to Animals Act of 1876, which highlights that experiments on animal species should only be carried out if necessary to save lives or alleviate pain and suffering. It mandates anesthesia and immediate sacrifice if an animal is injured or experiencing pain⁴.

On the other hand, plants are used by the global population to complement or satisfy their medical needs. The Nagoya Protocol complements the Convention on Biological Diversity, regulating appropriate access to biological resources and traditional knowledge. Among its many objectives is to provide standards regarding consent and required conditions that users and natural resources providers can agree upon, thereby contributing to the conservation of biological diversity and sustainable use⁵.

In research, ethics not only ensures respect for individuals but also constitutes an essential component of the methodological framework, guiding scientific development; however, it is often given superficial consideration⁶. Scientific publications must inherently embody integrity and uphold ethical standards in research. Consequently, the editorial process is responsible for identifying, preventing, and, when necessary,

addressing misconduct, which ensures the reliability and high quality of scientific knowledge⁷. Since promoting respect to ethical standards is a primary goal of medical journals, their publications must deliver tangible and reliable benefits. Therefore, it is imperative to include discussions on the ethics of scientific research and publication into both undergraduate and graduate professional education⁸.

Ethical research standards may vary among countries and across specific fields of knowledge, in terms of the requirements for conducting studies, the necessity of prior ethical appraisal, and the institutionalization of ethical review processes. Considering this diversity of scientific and institutional practices, as well as ethical pluralism, the international community has established ethical parameters and guidelines that must be universally respected⁷.

In Venezuela, bioethics emerged in 1995 under the guidance of Alfredo Castillo Valery, the first Venezuelan physician trained in bioethics. Along with other collaborators and interested parties, they formed a working group within the facilities of the Experimental School of Nursing of the Central University of Venezuela, which led to the formation of the Civil Association National Bioethics Commission (CENABI).

Since then, the development of this discipline has been gradual. Currently, bioethics in Venezuela is governed by the Code of Ethics for the Life of the National Fund for Science and Technology (FONACIT) and the Organic Law of Science, Technology, and Innovation (LOCTI), with contributions from institutional commissions such as the Venezuelan Institute of Scientific Research (IVIC) and CENABI⁹. However, prior studies have highlighted the lack of national-level bioethics committees in research¹⁰. This study thus aims to analyze the bioethical aspects of medical scientific production in Venezuela.

Method

This study consisted of a bibliometric analysis conducted on original articles in medicine

published in journals indexed on the Scopus and Web of Science (WOS) databases between 2018 and 2022, focusing on research originating from Venezuela involving humans, animals, or plants. The search engine for Scopus was: "TITLE-ABS-KEY-AUTH(Venezuela) and PUBYEAR>2017 and PUBYEAR<2023 and (LIMIT-TO(DOCTYPE "ar")) and (LIMIT-TO (AFFILCOUNTRY, "Venezuela)) and (LIMIT-TO (SUBJAREA, "MEDI"))". For WOS, the search engine was: "TS=(Venezuela) and VENEZUELA(Countries/Regions) and Article (Document Types) and 2022 or 2021 or 2020 or 2019 or 2018 (Publication Years)."

The articles were downloaded from both databases into Microsoft Excel documents using Windows 2016. Duplicate articles were removed using Rayyan manager. Following cleansing, a total of 1,904 original articles were obtained: 466 from Scopus and 1,895 from WOS. This process followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Figure 1)¹¹.

Inclusion criteria were: original research articles produced in Venezuela and carried out on humans, animals, and plants, published in Venezuelan or international journals between 2018 and 2022. Exclusion criteria were: clinical case reports and letters to the editor, review articles, articles unrelated to medical practice, articles in which study variables were not identified, and restricted access articles.

The study variables were: number of Venezuelan and foreign authors, year of publication, language of publication, journal origin (Venezuelan or foreign), national author affiliation by institution and Venezuelan state, and if it had approval from the research ethics committee, name of the research ethics committee, research ethics committee origin (Venezuelan or foreign); for Venezuelan research ethics committees, details of the institution and Venezuelan state,

and declaration of informed consent use. Affiliations were standardized according to hospital, research institute, or university; different departments within universities were categorized in their respective institutions. Due to the nature of the study, approval from a research ethics committee was deemed unnecessary.

Data was collected and collated using Microsoft Excel. Statistical analysis was completed using IBM SPSS Statistics. The R^2 value (coefficient of determination) was used to determine how well the data fit the growth line regression model in scientific production. Figures and contingency tables of frequency and percentage were constructed. Mann-Whitney's U test was used to compare independent group means; the Chi-square test and the exact mean p test to compare associations between quantitative and qualitative variables. Statistical significance was set as $p<0.05$, with a 95% confidence interval.

Results

The search strategy yielded 2,361 results, of which 523 records were ultimately included, as depicted in Figure 1.

The included articles involved the work of 3,686 authors, of whom 63% were affiliated with a Venezuelan institution. The distribution by year of the included studies is detailed in Figure 2, revealing a second-degree polynomial trend in publications between 2018 and 2022, with a 0.58 R^2 value. This indicates a mild to moderate correlation between the year and the number of publications from Venezuelan institutions in the medical field during this period.

Of the analyzed articles, 69.4% ($n=363$) were published in foreign journals, with 51.8% ($n=271$) of the manuscripts published in English.

Figure 1. PRISMA Flow chart. Identification of new studies via databases and registers

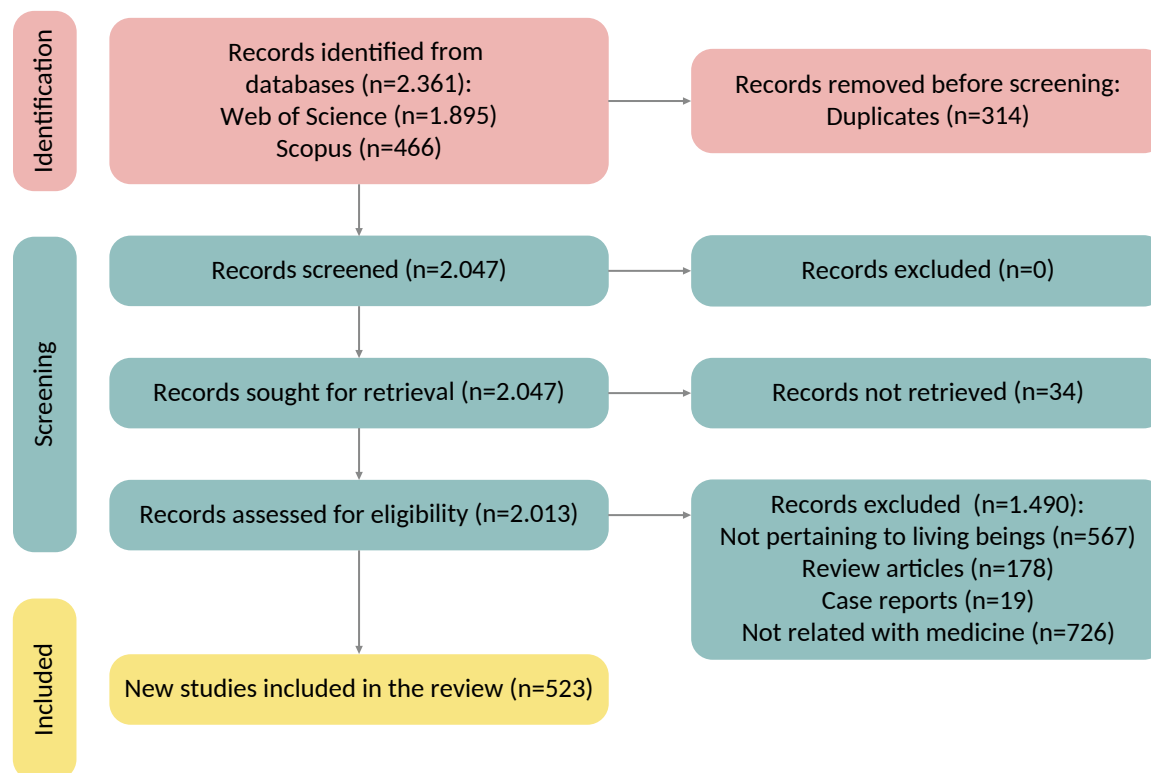
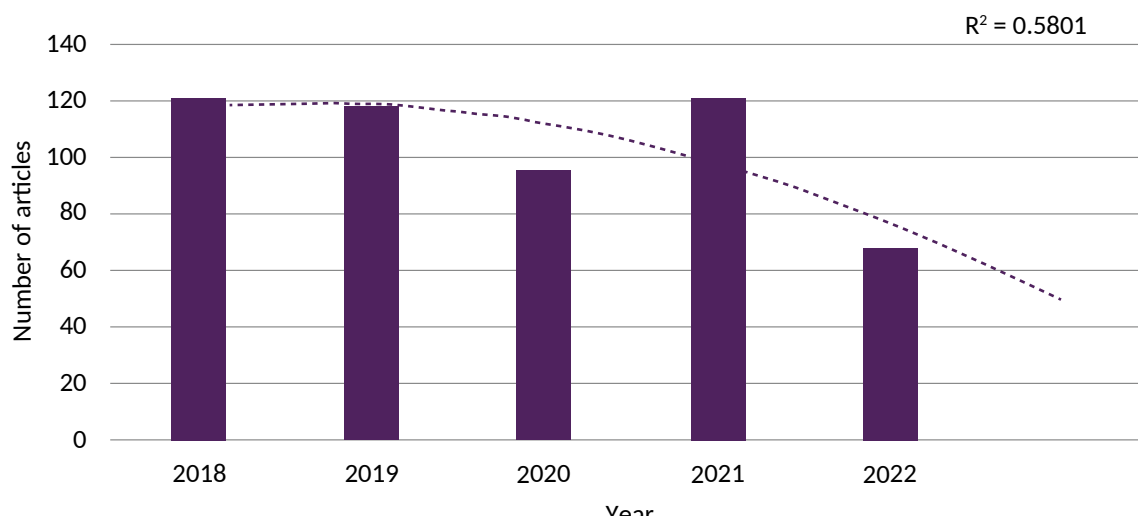


Figure 2. Scientific production in the medical field from Venezuela 2018–2022



Filiation

In descending order, the states with the greatest number of published articles based on the location of their institutions were Capital District

(Caracas), Zulia State, Carabobo State, Mérida State, Lara State, Bolívar State and Aragua State. Figure 3 provides a map of Venezuela detailing the density of published articles by state.

Figure 3. Absolute distribution of medicine-related articles by state in Venezuela, 2008–2022

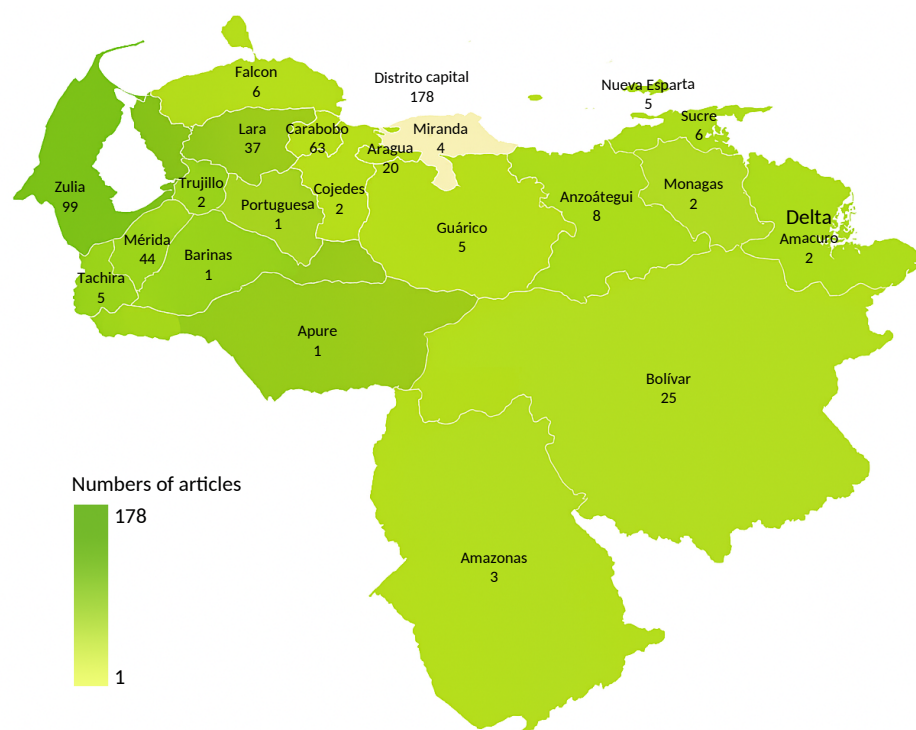


Table 1 summarizes the main universities and institutes/hospitals that stand out in the affiliations of the analyzed articles. Among universities, Universidad

de Oriente consolidates the scientific production from its various campuses, with the Bolívar State campus showing the highest production.

Table 1. Institutional affiliation in medicine-related scientific production in Venezuela 2018–2022

Research Center / Hospital	n (%)	Universidad	N (%)
IVIC	17 (3.3)	UCV	109 (20.8)
Hospital Central Dr. Urquinaona.	10 (1.9)	LUZ	67 (12.8)
Hospital Universitario de Caracas	10 (1.9)	UC	64 (12.2)
Instituto de Altos Estudios “Dr. Arnoldo Gabaldón”	6 (1.1)	ULA	39 (7.5)
Asociación de Asuntos Sociales e Impacto Civil	3 (0.6)	UCLA	32 (6.1)
Hospital Militar Dr. Carlos Arvelo	3 (0.6)	UDO	32 (6.1)
Hospital Universitario de Maracaibo	3 (0.6)	USB	9 (1.7)
Hospital Uyapar	3 (0.6)	UNEFM	4 (0.8)
Instituto de Biomedicina “Dr. Jacinto Convit”	3 (0.6)	UNERG	3 (0.6)
Instituto de Oncología “Dr. Luis Razetti”	3 (0.6)	UNELLEZ	2 (0.4)

IVIC: Instituto Venezolano de Investigación Científica; UCV: Universidad Central de Venezuela; LUZ: La Universidad del Zulia; UC: Universidad de Carabobo; UCLA: Universidad Centroccidental “Lisandro Alvarado”; UDO: Universidad de Oriente; USB: Universidad Simón Bolívar; UNEFM: Universidad Nacional Experimental Francisco de Miranda; UNERG: Universidad Nacional Experimental de los Llanos Centrales Rómulo Gallegos; UNELLEZ: Universidad Nacional Experimental de los Llanos Occidentales “Ezequiel Zamora”. % based on the total number of items included (n=523).

Of the total number of studies analyzed, 49.3% (n=258) reported having received approval from an ethics committee. Among these, 81.8% (n=211) were Venezuelan ethics committees.

The institutions whose ethics committees were most utilized are primarily located in the Capital District, where 74 of the analyzed articles were assessed, notably including the National Bioethics Center (CENABI), the Venezuelan Institute of Scientific Research (IVIC), and the Ethics Committee of the “Dr. Félix Pifano” Institute of Tropical Medicine at UCV. In Zulia State, 59 articles were evaluated by notable committees including the LUZ Institutional Review Board, the Ethics Committee of the “Dr. Urquinaona” Central Hospital in Maracaibo and the Bioethics Committee of the LUZ Faculty of Medicine.

Moreover, in Carabobo State, 24 articles were evaluated by the following notable committees:

the Bioethics Committee of the Biomedical Research Institute of the University of Carabobo (BIOMED-UC), and the Research Ethics Committee of the Hospital City “Dr. Enrique Tejera” in Valencia.

The main country whose foreign ethics committees were used was the United States, with six articles submitted for review. In 14.5% (n=76) of cases, institutions where the articles were produced relied on external ethics committees. The most frequent cases, based on the state of origin of the institution, were institutions in Caracas, Zulia State, and Mérida seeking approval from foreign ethics committees, and institutions in Aragua State seeking approval from institutions in Carabobo state.

The comparison between the characteristics of studies that reported approval by an ethics committee versus those that did not is presented in Table 2.

Table 2. Characteristics of medicine-related scientific production in Venezuela 2018–2022 based on their ethical committee approval status

Characteristics ^a	Approved by an ethical committee			
	Total (n=523)	No (n=265)	Yes (n=258)	p-value
Number of local authors	4 (2-6)	3 (2-6)	4 (2-6)	0.032 ^b
Number of foreign authors	0 (0-3)	0 (0-2)	1 (0-4)	0.003 ^b
Published in Venezuelan journals	160 (30.6)	99 (37.4)	61 (23.6)	<0.001 ^c
Language				
Spanish	238 (45.5)	140 (52.8)	98 (38)	<0.001 ^c
English	271 (51.8)	115 (43.4)	156 (60.5)	
Affiliation (by state)				
Distrito Capital	178 (34)	86 (32.5)	92 (35.7)	0.439 ^c
Zulia	99 (18.9)	33 (12.5)	66 (25.6)	<0.001 ^c
Carabobo	63 (12)	41 (15.5)	22 (8.5)	0.014 ^c
Mérida	44 (8.4)	29 (10.9)	15 (5.8)	0.034 ^c
Lara	37 (7.1)	23 (8.7)	14 (5.4)	0.147 ^c
Bolívar	25 (4.8)	10 (3.8)	15 (5.8)	0.274 ^c
Apure	20 (3.8)	10 (3.8)	10 (3.9)	0.951 ^c
Foreign country	4 (0.8)	0 (0)	4 (1.6)	0.058 ^d
Informed consent used	293 (56)	87 (32.8)	206 (79.8)	<0.001 ^c
Studies with human subjects	429 (82)	189 (71.3)	240 (93)	<0.001 ^c

^a Continuous data are shown as the median and interquartile range, and categoric data as number (%); ^b Mann–Whitney U test;

^c Chi-square; ^d Mid-P exact

Discussion

The findings demonstrate that just over half of biomedical publications resulting from research conducted in Venezuela do not declare project approval by a research ethics committee. This result mirrors trends observed in studies conducted in Turkey¹² and Iran¹³. Similarly, a study by Godskesen and collaborators found that respondents in the fields of Medical and Biological Sciences exhibit the highest frequency of research misconduct practices compared to other disciplines¹⁴.

In contrast to findings reported by Godskesen and collaborators in Sweden and Norway, or Wu and collaborators in China, in the fields of palliative care and nursing, respectively, a significantly smaller proportion omitted ethics committee approval, despite being published in leading high-impact nursing journals^{14,15}. This may indicate that in specific areas in which bioethical standards are highly regarded, such as end-of-life care, greater consideration is given to evaluation by a research ethics committee.

In contrast, the study by Godskesen and collaborators mentions that few scholars in Arts and Humanities admitted to engaging in research misconduct¹⁴. However, concerning falsification, these scholars exhibit the highest estimated prevalence, which suggests that while few academics in this field admitted to falsifying data, the proportion is higher. This leads us to consider that, in Biomedical Sciences, while overlooking research ethics committee involvement is common, there is usually a conscientious effort to avoid misconduct.

In the present study, 18% of studies with ethics committee approval were from international institutions, indirectly reflecting foreign collaboration in research and highlighting the lack of Venezuelan institutions regulating ethical aspects of research, which vary according to the study population and the laws of each country¹⁶.

In 44% of studies, informed consent was not reported, a result that differs from findings in similar studies in which 13%¹⁴ and 12.5%¹⁵ of published studies did not report obtaining informed consent from participants. While some studies may be exempt from ethics committee

approval due to their nature, it is the committee's responsibility to determine such exemptions. Therefore, it is crucial that all studies involving any living beings undergo review by a research ethics committee or appropriate body to approve the project¹⁷.

A documentary analysis of the situation in Venezuela demonstrates the lack of compliance with bioethical principles in national research development, alongside efforts by some universities to train human resources personnel in bioethics¹⁸. However, institutions with ethics committees that reviewed and approved projects for scientific publications during the studied period are predominantly located in the Capital District (Caracas), followed by the states of Zulia, Carabobo, Mérida, Lara, Bolívar, and Aragua, finding a gap in other states of Venezuela. One proposed measure to address this situation, akin to Costa Rica's approach, suggests that institutions establish a research ethics committee, with mandatory approval by the corresponding ethics committee as a fundamental requirement for affiliation in any scientific communication¹⁹.

In Latin America, Venezuela shows a 13% decrease in scientific production for 2021 compared to 2015, similar to Argentina and Cuba, with Brazil and Mexico leading as the region's most productive countries²⁰. Consequently, conducting studies that result in publication in prestigious indexed journals becomes increasingly challenging, particularly in fully complying with bioethical aspects for research execution.

Educational institutions and research-focused entities were both found to be actively producing scientific material. Many affiliations were associated with studies conducted at universities, indicating an interest in contributing to the scientific community and fostering the very career development of researchers²¹. Considering this as one of the functions of these centers, ethical guidelines should not merely be recommendations but must also be translated into practice²², becoming an intrinsic part of daily activities, in both their implementation and compliance evaluation.

Considering that slightly more than half of the publications in Venezuela do not declare ethics committee approval, it should be noted that there

is a lack of institutional engagement in preventing misconduct, which is an irrevocable part of their scientific duty²³. Furthermore, Bolland and collaborators mention that integrity in publication and good research practices are not solely the responsibility of researchers but also of universities, institutions, editors, reviewers, and readers, ultimately impacting the entire community²⁴.

Prior approval of these studies by a committee is essential, as it ensures compliance with ethical principles, legal respect for participants' rights, methodological quality, and a safe execution. The premise is that if a study is methodologically incorrect, it will not be ethically acceptable¹⁷. This demonstrates that in Venezuela, the Capital District has given much more consideration to this aspect, supported by its institutions when engaging in scientific aspects, suggesting that bioethics in Venezuela is still in an assimilation stage. Moving forward, efforts are needed to advance and standardize good bioethical practices for research development across the diverse states of Venezuela.

Final considerations

There was evidence of deficiencies in compliance with ethical aspects for the development of biomedical research in Venezuela based on high-impact databases spanning the studied five-year period. The highest frequency of articles mentioning ethics committee approval and informed consent was observed in studies conducted in Caracas, highlighting the lack of research ethics committees in other states of the country. Furthermore, there is a national deficiency in specialized ethics committees for research involving animals and plants, as well as regulatory norms in research and scientific integrity.

In this regard, the following is recommended: strengthening research ethics committees at the national level, decentralizing bioethical oversight of research protocols, strictly regulating informed consent, aligning them with international regulations, and incorporating bioethics into scientific and professional training.

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Jesus Brito-Nuñez – PhD – jedabritox@gmail.com

 0000-0001-6600-7377

Paola Estephania Guerra Di Bonaventura – PhD – paolaguerradi@gmail.com

 0000-0002-0460-072X

Yeisson Rivero-Moreno – PhD – yeissonmbi@hotmail.com

 0000-0002-9077-1460

Roxana Naimi Moreno-Brito – PhD – morenonaimi@gmail.com

 0009-0007-4923-1925

Wilman Alexander Maurera-Díaz – PhD – wilmana.a.maurera@gmail.com

 0009-0000-6377-0334

Yasmin Piña – PhD – jzzfilth@gmail.com

 0009-0006-1573-0382

Saiddys Daniela López-Lezama – PhD – saiddys.lopez@gmail.com

 0000-0001-9795-4596

Andrea García – PhD – andreagarcianu@gmail.com

 0000-0002-6586-522X

Paola Klaretsy Losada Muñoz – PhD – klaretsy@gmail.com

 0009-0009-9120-0203

Stephanie Daniela Molina-García – PhD – santiagobjgarzon@gmail.com

 0009-0000-8726-1577

Jesus Santiago Bautista-Garzon – PhD – sdanielamolina@gmail.com

 0009-0000-0855-2182

Correspondence

Jesus David Brito-Nuñez – Edif. Uriman 1, apt. 10-B Ciudad Guayana. CEP 8050. Estado Bolívar, Venezuela.

Participation of the authors

Jesús David Brito-Nuñez and Paola Estephania Guerra Di Bonaventura: research idea, drafting of the project. Jesús Brito-Nuñez, Paola Estephania Guerra Di Bonaventura, Yeisson Rivero-Moreno, Roxana Naimi Moreno-Brito, Wilman Alexander Maurera-Díaz, Yasmin Piña, Saiddys Daniela López Lezama, Andrea García, Paola Klaretsy Losada Muñoz, Stephanie Daniela Molina-García, Jesús Santiago Bautista-Garzón: data collection, data verification, drafting of the final version, and approval. Data analysis by Jesús Brito-Núñez and Yeisson Rivero-Moreno.

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