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BIOETHICS IN HEALTH RESEARCH

Liricis Yamara Zambrano Loor[1]*, Ingeborth Jhosefine Vélez Zeballos[1], Maria Felicidad Vélez Cuenca[1], Nube Sanmartin Matute, MG[1], Maria José Muentes Vélez[2], Shirley Agustina Sánchez Sánchez[1]

[1]Universidad Técnica de Manabí
[2]Universidad de Cuenca

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Corresponding Author: Liricis Yamara Zambrano Loor (liricis.zambrano@utm.edu.ec)

ABSTRACT

Bioethics in health research seek to establish ethical principles to guide scientific practice, especially in contexts involving human subjects. Since its inception, bioethics has evolved in response to the ethical crises and scandals that have marked the history of medicine and research. The need to protect the rights and dignity of participants in clinical studies has led to the creation of regulations governing biomedical research, highlighting the importance of informed consent and risk minimization. To analyze the main modern ethical challenges in health research and propose strategies to strengthen normative frameworks and the implementation of bioethical principles. This study was conducted using a qualitative, descriptive approach based on a review of recent scientific literature. Sources selected include peer-reviewed articles, regulatory documents, and books addressing ethical principles, regulatory frameworks, and emerging challenges in health research. Health research faces a variety of ethical challenges that require deep reflection and a comprehensive approach to ensure that scientific progress is carried out responsibly and with respect for human rights. Globalization, technological advances, and the recent COVID-19 pandemic have highlighted the need to strengthen bioethics, especially in regions such as Latin America, through a continuous commitment to ethical principles and global bioethics education.

KEYWORDS: bioethics, ethical issues, ethical regulation, health, informed consent.

1 INTRODUCTION

Bioethics in health research is an interdisciplinary field aimed at establishing ethical principles to guide scientific practice, especially in contexts involving human beings. Since its beginnings, bioethics has evolved in response to ethical crises and scandals that have shaped the history of medicine and research. The need to protect the rights and dignity of participants in clinical studies has led to the creation of regulations governing biomedical research, emphasizing the importance of informed consent and risk minimization (1).

One of the pillars of bioethics is the principle of informed consent, which ensures that research participants fully understand the objectives, risks, and benefits of their participation. This principle not only respects individual autonomy but also promotes a relationship of trust between researchers and participants. Bioethics emphasizes that research must be justified both socially and scientifically, ensuring that the benefits outweigh potential risks (2).

Furthermore, bioethics addresses equity in the selection of research participants. It is crucial that all populations—particularly those in vulnerable situations—have equitable access to the benefits of research. This includes considering socioeconomic and cultural factors that may influence participation and well-being (3,4). Failure to attend to these aspects can lead to the exploitation of disadvantaged groups, a recurring concern in ethical debates.

The regulation of health research has also become a topic of growing interest in Ibero-America, where significant institutional development has been observed in recent decades. This growth has been driven by the need to establish regulatory frameworks that protect participants' rights and ensure scientific integrity. Bioethics institutions in the region have begun to address emerging topics, such as the impact of technology on health and research, as well as the need for greater inter-institutional collaboration to promote a robust bioethical culture (3,6).

It is important to note that bioethics should not be seen as an obstacle to research but as an essential component that enriches the scientific process. Integrating bioethical principles into research not only improves the quality of studies but also fosters public trust in science. Thus, bioethics acts as a bridge between research and social responsibility, ensuring that scientific advancement is carried out ethically and with respect for human rights (4,5).

2 METARIALS AND METHODS

2.1 Search Strategy

The search strategy was exhaustive, designed to identify relevant literature on ethical challenges in health research. Electronic databases such as PubMed, Elsevier, SciELO, and Google Scholar were used, employing key terms in Spanish like "Bioética," "Consentimiento informado," "Investigación en salud," and "Regulación ética," as well as English terms such as "Bioethics," "Ethical Regulation," "Health Research," and "Informed Consent." The strategy was adapted to the syntax of each database, and Boolean operators were used to enhance the accuracy and efficiency of the search.

2.2 Inclusion and Exclusion Criteria

The inclusion criteria were defined systematically and included: qualitative articles, systematic reviews, and books addressing ethical challenges in health research; written in English, Spanish, or Portuguese; published between 2019 and 2024; and with full-text availability, including both open-access and paid articles. Works that did not specifically address bioethics in health research or did not meet the defined temporal and linguistic criteria were excluded.

3 RESULTS

In summary, the findings show that health research relies on strong bioethical values but faces normative, structural, and operational challenges that impact study integrity. We observed the coexistence of multiple legal frameworks, resource disparities among ethics committees, frequent tensions between technological innovation and rights protection, and a global context—marked by the pandemic and health inequalities—that underscores the urgency of advancing toward more integrated and forward-looking bioethics.

Table 1. Summary of indicators and observations by thematic axes in bioethics of health research

Thematic Axis	Relevant Indicator	Value or Observation	Reference
Ethical Aspects	Application of bioethical principles	Beneficence 41.82%; non-maleficence 30.29%; Justice 17.31%; Autonomy 10.58%	(1), (7)
Regulation and Standards	Legal fragmentation	Multiple laws and guidelines without harmonization in Mexico and Colombia	(4), (8), (9), (10)
Ethics Committees	Number of NECs/CEISH and regional institutions	124 NECs in 100 countries; 157 Ibero-American institutions	(3), (11), (12)
Ethical Challenges	Internists with frequent ethical	70% face dilemmas; 50% have difficulty	(5), (13), (14), (15)

	conflicts	resolving them	
Scientific Integrity	Need for infrastructure and cross-cutting training	CEI/CEIm in Spain require legal, institutional, and educational reinforcement	(15), (17)
Technological Innovation	Transparency and data protection in AI	Risks of genetic identifiability and discrimination	(16), (18)
Current Context	Post-COVID holistic bioethics	Integration of human rights, civic duties, and social and ecological sustainability	(1), (19)
Emerging Challenges	Global ethics repository and 3Rs in animal research	Proposal for an Ibero-American Observatory and global repository of NECs; adoption of 3Rs principles	(10), (11), (19)
The Need for a Holistic Approach	Integration of social, cultural, economic, and environmental dimensions in bioethics	Urgent need to integrate social, cultural, economic, and environmental dimensions into a unified bioethics framework	(19), (20)
Training and Capacity Building in Bioethics	Imperative to strengthen continuous education in values, methods, and conflict resolution	A lack of ongoing education for researchers and evaluators limits the management of ethical dilemmas	(5), (12), (21)
Future of Bioethics in Health Research	Projection toward collaborative models, deliberation repositories, and dynamic 21st-century frameworks	Movement toward collaborative models, dynamic repositories, and flexible frameworks for the 21st century	(11), (12), (20), (21)
Source: Literature Review			

4 DISCUSSION

4.1 Ethical Aspects in Health Research

The protection of participants' privacy and data confidentiality is a critical ethical aspect. Researchers must ensure that the personal and medical information of subjects is kept secure and confidential, and used only for the purposes of the study. This involves employing adequate security measures, such as encrypted data storage and restricted access to information (7).

Beyond these general principles, health research must also consider specific ethical aspects depending on the type of study and population involved. For example, research involving vulnerable groups—such as children, individuals with mental disabilities, or prisoners—requires additional safeguards to protect their rights and well-being. Similarly, studies involving biological samples or invasive procedures must follow specific ethical guidelines (1).

4.2 Regulation and Ethics in Health Research

Ethical regulation in health research is essential to ensure both safety and scientific integrity when human beings are involved. In Latin America and globally, several instruments and ethics committees play a key role in this process:

1. General Health Law: In countries such as Mexico, this law outlines ethical and scientific guidelines for health research. The regulations emphasize strict control mechanisms to protect research participants' health (8).
2. Regulations on Ethics Committees: In Ecuador and other countries, specific regulations govern how Human Research Ethics Committees (HREC) are formed and function. These ensure that all studies involving human subjects are ethically and methodologically assessed (9).
3. International Standards: Declarations such as Helsinki and CIOMS guidelines provide a foundation for ethical health research adopted by many nations in their legislation (10).

4.3 Ethics Committees

National Ethics Committees (NECs) are vital for providing oversight and guidance on ethical issues in medicine and biomedical research. One study identified 124 NECs in 100 countries, highlighting their role in deliberating bioethical matters—including research (11). These committees are crucial for addressing ethical dilemmas arising from technological advancements and multinational research collaborations.

4.4 Ethics Committees in Latin America

In Latin America, HRECs are tasked with evaluating research protocols to protect the dignity and rights of participants. However, ethical standard implementation varies significantly between countries. Challenges include lack of funding and personnel in some areas. A study on HRECs in the region noted that while guidelines exist, their application is often inconsistent and resource-constrained (12).

4.5 Informed Consent

Informed consent is a cornerstone of research ethics because it ensures respect for the autonomy of participants (13). This process enables individuals to make informed decisions about their participation, based on a clear understanding of the risks, benefits, and alternatives. However, in practice, achieving truly informed consent remains a persistent

challenge. Researchers must communicate complex information in an accessible way to ensure participants fully understand the study's details. This becomes especially difficult among populations with low literacy levels or in multicultural settings, where language and cultural barriers may hinder comprehension. Furthermore, informed consent is not a one-time event but an ongoing process, updated and reaffirmed as the study progresses or if circumstances change (14).

4.6 Justice in Participant Selection

Justice in the participant selection is a fundamental principle aimed at preventing the exploitation of vulnerable populations and ensuring equitable distribution of research burdens and benefits. This becomes particularly important in studies conducted in low-resource settings, where people may be more susceptible to exploitation due to a lack of alternatives or limited resources. Researchers must be especially careful not to take advantage of such inequalities. In studies of rare or orphan diseases, there is also an ethical dilemma: the small number of affected individuals can lead to their repeated involvement in multiple studies, exposing them to repeated risks. Ethics committees must carefully evaluate these issues to ensure participant selection is fair and just (15).

4.7 Minimization of Risks

Risk minimization is another central ethical obligation in research. It involves identifying and reducing possible physical and psychological harm, as well as socio-economic repercussions for participants. Yet there's an inherent tension between the need to minimize risks and the need to produce meaningful data that can advance scientific knowledge. This is particularly evident in studies involving innovative or experimental interventions, where risks and their consequences may be unknown. In such cases, researchers and ethics committees must carefully assess whether the potential benefits sufficiently justify exposing participants to possible dangers. Continuous risk assessment throughout the study is also essential to allow for adaptations—or even suspension—if the risks begin to outweigh the benefits (16).

4.8 Confidentiality and Privacy

Protecting the confidentiality and privacy of participant data is essential to maintain public trust in scientific research (13). With the rise of digital technologies and large databases, new challenges have emerged regarding data security. Breaches can have serious consequences, including the exposure of sensitive information that could be used to harm, discriminate against, or exploit participants—particularly in genetic or mental health studies. Researchers must implement robust security measures and be prepared to respond to potential confidentiality breaches (14). They should also clearly explain to participants how their data will be handled, stored, and protected, making sure participants understand potential risks and the strategies in place to mitigate them.

4.9 Scientific Integrity

Scientific integrity is a foundational principle that ensures the validity and reliability of research outcomes (15). Researchers have an ethical responsibility to design well-founded studies, collect and analyze data rigorously, and report findings accurately and honestly. Unfortunately, pressure to publish or compete for funding may tempt some to compromise these principles, engaging in unethical conduct such as data fabrication, plagiarism, or result manipulation. Scientific misconduct not only damages the credibility of the individual researcher but can also have serious consequences for public health if policy decisions are based on flawed studies. Institutions must promote a culture of scientific integrity and put clear mechanisms in place to detect and sanction misconduct (17).

4.10 Technological Innovation

New technologies such as artificial intelligence (AI) and genomic sequencing have revolutionized biomedical research, opening new possibilities for diagnosing, treating, and preventing diseases. However, these innovations also present unique ethical challenges. For example, AI used in analyzing large datasets can lead to automated decisions that directly affect individuals' health, raising questions about responsibility and transparency (16). Likewise, genomic sequencing enables the identification of genetic predispositions, which may result in genetic discrimination or ethical dilemmas about disclosing information to participants and their families. Researchers must remain aware of these challenges and proactively work to develop and implement ethical frameworks that guide the responsible use of emerging technologies (18).

4.11 Current Context of Bioethics in Research

Historically, bioethics has emerged as a response to ethical crises arising from inappropriate research conduct. Past scandals have spurred the development of regulations aimed at protecting

participant rights and ensuring scientific integrity. Current bioethical recommendations focus on protecting human rights, participant safety, treatment efficacy, and conducting studies ethically. One of the most emphasized aspects today is the need for ethical consensus to ensure that research is not only scientifically valid but also socially justified. This means every study must have a clear purpose aimed at improving people's quality of life (1). Bioethics should be seen as an ally in the pursuit of knowledge, fostering an approach that respects human dignity at all times.

4.12 Emerging Challenges

The COVID-19 pandemic has highlighted the relevance of bioethics in health research by exposing new ethical dilemmas. The urgency to develop and distribute vaccines raised questions about equitable access to treatments and prioritization of vulnerable groups. Bioethics had to adapt quickly, promoting a holistic vision that incorporates not only health but also the social, economic, and political factors that affect people's lives (19).

A significant challenge lies in the integration of technology into research. The use of AI and big data in healthcare raises concerns about personal data privacy and security. Bioethics must address how this data is managed and ensure that participant rights are respected—especially in a context where information may be used in ways that are not always transparent or ethical (19).

4.13 The Need for a Holistic Approach

Contemporary bioethics must adopt a holistic approach that considers the interrelationships between health, environment, economy, and human rights. This approach is essential for addressing complex issues such as inequality in healthcare access and social justice. Bioethics should not focus solely on biomedical aspects but also reflect on the social impact of decisions made in the health field (20).

The UNESCO Universal Declaration on Bioethics and Human Rights highlights the importance of equity and justice in healthcare, stressing that access to health is a fundamental human right. In this context, bioethics must work to ensure that all individuals—regardless of their socioeconomic status—have access to the healthcare they need (20).

4.14 Bioethics Education and Training

Education and training in bioethics are essential to prepare health professionals and researchers to face the ethical dilemmas of their daily practice. Creating continuing education programs and integrating bioethics into academic curricula are necessary steps to foster a culture of respect for research participants' rights. Ecuador's National Commission of Bioethics in Health, for instance, has launched numerous educational initiatives and recommendations to improve bioethics training. Raising public awareness of bioethical issues is also crucial. Promoting public debate on these topics can increase awareness and understanding of patient rights and the ethical dimensions of research.

4.15 Future of Bioethics in Health Research

Looking ahead, bioethics in health research must continue to evolve to adapt to changes in society and science. Globalization and technological advances present new challenges that require international collaboration and interdisciplinary dialogue. Bioethics must be a dynamic field that not only responds to existing problems but also anticipates future dilemmas and seeks proactive solutions (20).

Furthermore, bioethics must be integrated into the development of public health policies, ensuring that decisions in this field are grounded in strong ethical principles. This includes the prioritization of limited resources and the fair allocation of treatments, especially in crisis situations such as the COVID-19 pandemic (21).

5 CONCLUSIONS

Health research faces a variety of ethical challenges that demand deep reflection and a comprehensive approach to ensure that scientific advancement is carried out responsibly and with respect for human rights. Throughout this analysis, key aspects have been emphasized—such as informed consent, justice in participant selection, risk minimization, data confidentiality and privacy, scientific integrity, and regulatory frameworks. Each of these elements plays a crucial role in building a solid ethical foundation to guide health research toward sustainable and equitable development.

Globalization and technological advances—such as artificial intelligence and genomic sequencing—have raised new dilemmas that must be proactively addressed. While these innovations are promising, they also require the creation and application of ethical frameworks to ensure their implementation does not compromise participants' rights and dignity. Moreover, the COVID-19 pandemic has made clear the need for a form of bioethics that not only responds to current challenges but is also prepared to face future ethical dilemmas in times of crisis.

Strengthening research ethics committees, particularly in regions like Latin America, is essential to ensure the protection of participants in biomedical studies. However, it is evident that there are variations in how ethical standards are implemented, underscoring the need for a more uniform and rigorous global approach.

Education and training in bioethics are essential pillars to equip researchers and healthcare professionals to navigate ethical dilemmas with awareness and responsibility. Promoting a culture of scientific integrity and respect for research participants' rights must be a priority at all levels of scientific inquiry.

Looking ahead, bioethics must continue to evolve, integrating itself into public policy development and anticipating emerging challenges in science and society. Only through sustained commitment to ethical principles and an interdisciplinary approach can health research truly benefit humanity in a fair and equitable way.

BIBLIOGRAPHIC REFERENCES

Bustos Saldaña R. Validación de un instrumento para la aplicación de los principios bioéticos principialistas en los protocolos de investigación clínica. Acta Bioeth [Internet]. 2024 [cited 2024 Sep 1];30(1):95–105. Available from: https://www.scielo.cl/scielo.php?pid=S1726-569X2024000100095&script=sci_arttext

¿Qué es la bioética en la investigación? Entrevista a Carlos Herraiz [Internet]. Universidad Europea. 2023 [cited 2024 Sep 1]. Available from: https://universidadeuropea.com/blog/bioetica-investigacion/

Cabrera Cabrera A, Sánchez Guerrero A, Cerdio Domínguez D, Fernández Molina MV. Desarrollo institucional de la bioética en Iberoamérica: resultados preliminares del Atlas Iberoamericano de bioética. Med Etica [Internet]. 2024 [cited 2024 Sep 1];35(2):484–536. Available from: https://www.scielo.org.mx/scielo.php?pid=S2594-21662024000200484&script=sci_arttext

Hugo Nelson Castañeda Ruiz HN, Gómez Osorio ÁM, Londoño Jaramillo ÁM. Reflexiones sobre la ética de la investigación en Colombia. Agora U S B [Internet]. 2020 [cited 2024 Sep 1];20(2):283–97. Available from: http://www.scielo.org.co/scielo.php?pid=S1657-80312020000200283&script=sci_arttext

Pérez Rueda M, Palacios García-Cervigón G. Los retos de la bioética en la práctica clínica del siglo xxi. Rev Clin Esp [Internet]. 2021 [cited 2024 Sep 1];221(7):406–7. Available from: http://dx.doi.org/10.1016/j.rce.2020.06.010

Betancourt Torres I, Alpízar Caballero LB, Panesso Patiño V. Integración de ciencias y tecnología para la solución de problemas sociales en la cultura. Varona [Internet]. 2022 [cited 2024 Sep 1];(75). Available from: http://scielo.sld.cu/scielo.php?pid=S1992-82382022000200018&script=sci_arttext&tlng=en

Pacheco Moscoso G, Arteaga Sarmiento S, Andrade Campoverde D, Tenesaca Serpa A. Conflictos éticos en la fase pre analítica en los análisis clínicos. facsalud [Internet]. 2024;8(14):58–67. Available from: http://dx.doi.org/10.29076/issn.2602-8360vol8iss14.2024pp58-67p

Candia Plata M del C, Leverda González DJ, Pacheco Quiroz M, Vázquez Medina OH, Álvarez Hernandez G, López Soto LF. Bases jurídicas, normativas y éticas de la investigación en seres humanos, en México: Normativa de la investigación en seres humanos en México. Biotecnia [Internet]. 2024;26:233–40. Available from: http://dx.doi.org/10.18633/biotecnia.v26.2252

Preguntas frecuentes – CEISH – Ministerio de Salud Pública [Internet]. Gob.ec. 2022 [cited 2024 Sep 1]. Available from: https://www.salud.gob.ec/preguntas-frecuentes-ceish/

Rebuelto M. Una referencia valiosa para el uso responsable de los animales en la investigación científica: el documento guía "Principios rectores internacionales para la investigación biomédica con animales CIOMS-ICLAS." Rev Bioet Derecho [Internet]. 2022; Available from: http://dx.doi.org/10.1344/rbd2022.55.35939

Hummel P, Adam T, Reis A, Littler K. Taking stock of the availability and functions of National Ethics Committees worldwide. BMC Med Ethics [Internet]. 2021;22(1). Available from: http://dx.doi.org/10.1186/s12910-021-00614-6

Santos Castro CB, Bravo Pesántez CE. Situación Actual de los Comités de Ética de Investigación en Seres Humanos en Latinoamérica. Tesla rev cient [Internet]. 2023 [cited 2024 Sep 1];3(1):e193. Available from: https://tesla.puertomaderoeditorial.com.ar/index.php/tesla/article/view/194

De Montalvo Jääskeläinen F. Una reflexión desde la teoría de los derechos fundamentales sobre el uso secundario de los datos de salud en el marco del Big Data. Rev derecho político [Internet]. 2019;(106):43–75. Available from: http://dx.doi.org/10.5944/rdp.106.2019.26147

Ética en Investigación : nuevos desafíos, ¿viejos dilemas? / Adriel Jonas Roitman; contribuciones de María Laura Garau; Claudia Teresa Vukotich; Diseño o ilustración de cubierta de Benzaquen, Melina; Salvatierra Viader , Lucas Andres / - 1a ed. - Ciudad Autónoma de Buenos Aires : Gobierno de la Ciudad de Buenos Aires. Ministerio de Salud. Dirección General de Docencia, Investigación y Desarrollo Profesional, 2023.

Solis Sánchez G, Alcalde Bezhold G, Alfonso Farnós I. Ética en investigación: de los principios a los aspectos prácticos. An Pediatr (Barc) [Internet]. 2023;99(3):195–202. Available from:

Universidad Santiago de Cali, Bermeo de Rubio M, Pardo Herrera I, Universidad Santiago de Cali, Estrada González C, Universidad Santiago de Cali, et al. De la ética a la bioética en las ciencias de la salud. Editorial Universidad Santiago de Cali; 2020.

Zúñiga Vargas JP. Comportamiento ético en la publicación científica: malas conductas y acciones para evitarlas. Rev Educ [Internet]. 2019;16. Available from: http://dx.doi.org/10.15517/revedu.v44i1.35548

Paz-y-Miño C. La inteligencia artificial en medicina general y en genómica. MetroCiencia [Internet]. 2023 [cited 2024 Sep 1];30(2):81–6. Available from: https://www.revistametrociencia.com.ec/index.php/revista/article/view/562

Camargo Rubio RD. Visión holística de la bioética en la pandemia COVID-19. Acta Colomb Cuid Intensivo [Internet]. 2022 [cited 2024 Sep 1];22:S79–92. Available from: http://dx.doi.org/10.1016/j.acci.2021.03.003

Garrafa V. Bioética y el derecho al acceso a los cuidados de salud. Salud Colect [Internet]. 2023 [cited 2024 Sep 1];19:e4491. Available from: https://www.scielosp.org/article/scol/2023.v19/e4491/

Pacheco V. La comisión nacional de bioética en salud en Ecuador. La utopía de la defensa de la dignidad, la integridad y los derechos de las personas y comunidades. Práct fam rural [Internet]. 2019;4(3). Available from: http://dx.doi.org/10.23936/pfr.v4i3.130