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Review article

Research and Publication. Part 8. Basic Ethical Principles in Clinical Research: Essential Bioethical Considerations in Biomedical Investigation: Foundations, Standards, and Indispensable Practices

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Abstract

Biomedical research is a continuously evolving field whose primary purpose is to address current health needs. Today, the availability of advanced technoscientific tools offers new opportunities to improve diagnostic and therapeutic capabilities. This article outlines the fundamental ethical principles that govern clinical research, emphasizing their historical development, key international and national regulatory frameworks, and the contemporary challenges posed by emerging technologies such as artificial intelligence and personalized medicine. The seven criteria proposed by Emanuel et al.[1] are presented as a cornerstone for the ethical assessment of biomedical research protocols. The article also highlights the importance of bioethics training, the strengthening of Research Ethics Committees (RECs), and the cultivation of a broader culture of scientific integrity.

Keywords

Bioethics, clinical research protocol, ethics committees, informed consent, scientific integrity.

INTRODUCTION

Biomedical research has evolved as an essential tool for improving public health; however, it has also generated ethical challenges that require systematic reflection. Its impact is far-reaching and, therefore, integrating bioethics at every stage of the research process is an obligation to ensure respect for human rights, transparency, and justice. Bioethics in research is not limited to the individual protection of participating subjects; it extends to a social and collective responsibility regarding how knowledge is produced, how derived benefits are distributed, and who participates in decision-making. For these reasons, it is indispensable to analyze not only regulatory frameworks but also the philosophical foundations that underpin ethical practices in biomedical contexts. Accordingly, the question that explains the research ecosystem is: why is it necessary to integrate bioethics into biomedical research? In this regard, a brief historical overview is presented to highlight certain requirements necessary to comply with research ethics and scientific integrity.

Throughout history, in light of advances in knowledge and techno-scientific developments—which today enable and challenge the use of artificial intelligence, gene therapy, and personalized medicine, among others—research methodologies have been transformed, making it increasingly important to remain attentive to their impacts on human beings and, by extension, on humanity as a whole.

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METHODOLOGY

This work was conducted as a narrative, documentary-type review, grounded in a hermeneutic and deliberative bioethical approach. Primary and secondary sources were analyzed, including international codes (Nuremberg, Helsinki, Belmont, CIOMS), academic literature, and national regulatory frameworks, with the aim of identifying tensions between classical ethics and the emerging demands of contemporary biomedical research.

METHODOLOGICAL LIMITATIONS

The review does not include empirical data, which limits the practical corroboration of the findings. Nevertheless, this approach allows for a critical and cross-cutting understanding of the current ethical-regulatory framework, appropriate for the conceptual analysis of applied bioethics.

ETHICAL FOUNDATIONS OF CLINICAL RESEARCH

From its earliest beginnings, biomedical research has required the presentation of a methodology to carry out the best possible research project. While this is true, in its early stages research was not structured in this manner, as experiments were conducted without clearly defined objectives and hypotheses that could readily demonstrate such methodology as a requirement for compliance with biomedical research standards. This changed particularly following the recognition of the experiments conducted during the Second World War and the subsequent trial of physicians in Nuremberg, which prompted the implementation of methodological and ethical criteria in the conduct of biomedical research. It was then that international declarations emerged to guide biomedical research, such as the Nuremberg Code (1949)[2] and the Declaration of Helsinki (1964), along with its most recent update (2024)[3].

The Declaration of Helsinki is a set of ethical principles established by the World Medical Association (WMA) to guide medical research involving human participants. Its primary objective is to protect the dignity, rights, and well-being of individuals who participate in medical research. To this end, it requires the protection of life and health and respect for participant autonomy, and it promotes the minimization of risks and harms. Likewise, it fosters scientific integrity and ensures access to benefits, which is reflected in the research protocol and the informed consent process. Research protocols must be evaluated by a Research Ethics Committee (REC) and approved prior to the initiation of a study, thereby ensuring the transparent publication of research results. In its final section, the Declaration refers to interventions that are not approved in clinical practice. The Belmont Report[4], the International Ethical Guidelines for Biomedical Research (CIOMS)[5], the Declaration of Taipei[6], among others, constitute recommendations to which countries adhere through their internal regulations.

The regulatory framework that has gained the greatest visibility is the implementation of Good Clinical Practice (GCP) for research involving human beings and biomedical products, proposed by the World Health Organization (WHO) and the International Council for Harmonisation (ICH). These practices establish standards and guidelines for GCP. Accordingly, in Colombia, the National Institute for the Surveillance of Medicines and Foods (INVIMA), through Resolution 2378 of 2008[7], implemented GCP and required that, in order to conduct research, researchers must be members of a Research Ethics Committee or belong to a research center in order to obtain GCP certification.

Considering the regulatory framework and its evident appropriation for scientific production, it is essential to recognize the importance and sensitivity of scientific integrity. Today, there are publications reporting research retractions for various reasons; among the most frequent are plagiarism, misconduct, errors, fabrication, and duplication, all of which relate to scientific integrity. These issues generally arise from methodological doubts, problematic results, and ethical concerns that necessitate review, drawing attention to their increasing frequency. This underscores the importance of mitigating such issues through education and awareness regarding publication ethics and the responsible conduct of research by researchers and journal editorial teams[8].

The Belmont Report (1979)[4] promotes ethical principles and guidelines for the protection of human beings in research, which are reflected in informed consent. This document evidences the ethical and transparent process through which the autonomy of the research participant is recognized, freely, voluntarily, and consciously, as an expression of participatory acceptance in the research. Informed consent constitutes the informational evidence provided to the participant regarding the objectives of the research, and it is the responsibility of the principal researchers to inform the REC of how this information will be conveyed, whether through a clearly defined and robust encounter, requiring clear and accessible language delivered through videos or written texts. The informed consent document is validated by the signature of the participant, the principal researcher, and two witnesses, in accordance with Colombian regulations (Resolution 8430 of 1993 of the Ministry of Health, which establishes standards for health research)[9], thereby ensuring participant autonomy, the adequacy of the information provided, and respect for participant rights—fundamental requirements for obtaining informed consent. In addition, Law 23 of 1981[10], in

Article 10, establishes that informed consent must be obtained for any medical or surgical treatment that may physically or psychologically affect the patient. With respect to research, this medical ethics law refers to the recommendations of the WMA in Article 54, which states: "with regard to biomedical research in general, therapeutic research in humans, and the application of new technologies, whether for diagnostic purposes (…)". For this reason, the scope of the regulatory framework cannot be disregarded.

JUSTIFICATION OF ITS CURRENT RELEVANCE

Within this broad context that defines and shapes biomedical research, research ethics constitutes an indispensable requirement due to the direct involvement of human beings and the contribution of bioethics to understanding the care of life. Accordingly, it calls for reflection on all components of research and their future impacts. An additional component that strengthens the work of the researcher is scientific integrity, which aims to maintain trust and credibility in science through good practices in the generation and appropriation of knowledge[11].

ETHICAL CRITERIA FOR RESEARCH PROJECTS

Emanuel and colleagues[1] propose seven criteria for considering clinical research to be ethical, as presented in **Table 1**.

These criteria constitute the minimum ethical framework for designing and evaluating clinical research projects, and they are particularly useful for Research Ethics Committees when analyzing complex protocols with innovative methodologies or involving emerging technologies. In addition, they provide concrete guidance for researchers and promote an ethics of shared responsibility. Given the diversity of methodologies in biomedical research, adjustments in ethical evaluation are required, which invariably demand deliberative reflection within the research context.

CONTEMPORARY CHALLENGES AND NEW BIOETHICAL CONSIDERATIONS

Current challenges include research conducted in public health emergency contexts, as well as the use of artificial intelligence (AI), big data, genomics, and personalized medicine. These technologies require new ethical and legal regulations. The United Nations Educational, Scientific and Cultural Organization (UNESCO)[12] has issued recommendations, and in Colombia, CONPES 3975 of 2019[13] establishes guidelines for the use of AI.

The use of AI in ethical evaluation by Research Ethics Committees (RECs) raises new questions regarding algorithmic transparency, consent, and equity. For example, a lack of understanding of AI models by researchers or reviewers may lead to decisions based on opacity or unidentified biases. This reinforces the need for continuous training in the ethics of technology and for interdisciplinary technical evaluation.

Genetic research, gene editing (such as the use of CRISPR-Cas9), and data biobanks also demand new bioethical considerations, particularly with respect to privacy, broad consent, and future data use. Protection of the right not to know and the ethical management of the return of results have become key issues. It is crucial to anticipate potential dilemmas before they arise, fostering a prospective or anticipatory bioethics[14].

Current techno-scientific advances reconfigure traditional notions of consent, risk, and justice. The expansion of genetic biobanks, AI applied to health, and gene editing through technologies such as CRISPR-Cas9 generate unprecedented tensions with respect to classical principles.

Table 1. Ethical Criteria for Ethical Clinical Research according to Emanuel and Colleagues[1]

No.	Ethical Criteria	Summary Description
1	Social or scientific value	Research must contribute relevant knowledge to public health or science.
2	Scientific validity	The methodological design must be rigorous and appropriate to answer the research question.
3	Fair participant selection	Inclusion must be just and avoid the exploitation of vulnerable populations.
4	Favorable risk-benefit balance	Risks must be reasonable in relation to the expected benefits.
5	Independent review	An ethics committee must review and approve the protocol prior to its execution.
6	Informed consent	Participants must freely agree after understanding risks, benefits, and alternatives.
7	Respect for participants	Includes confidentiality, voluntary withdrawal, and access to results.

Adapted from: Emanuel EJ, et al. JAMA. 2000;283(20):2701-11[1].

Autonomy requires reinterpretation in light of broad and ongoing consent for secondary data use. Beneficence and non-maleficence face the epistemic uncertainty of new techniques, and justice takes on a global dimension in the context of unequal access to advanced therapies. These challenges call for an anticipatory bioethics capable of collectively deliberating on the limits and purposes of science.

RECOMMENDATIONS

- Strengthen bioethics training for researchers, including the ethics of technology, global justice, and cultural pluralism.
- Consolidate the role of ethics committees as active deliberative bodies with technical competence.
- Promote community participation in the research process, not only as subjects but as deliberative actors.
- Ensure effective communication among researchers, RECs, and regulatory entities.
- Foster scientific integrity at all stages of research, from design to publication and dissemination of results.
- Promote public policies that update regulatory frameworks in line with techno-scientific transformations.
- Include mechanisms for continuous monitoring and ethical audits to strengthen accountability in clinical research.

CONCLUSIONS

Clinical research must be conducted ethically and responsibly. Respect for human dignity, protection against harm, the pursuit of social benefits, and justice in participant selection are indispensable pillars. Good practices must be reflected in informed consent, transparency of results, confidentiality, and ethical oversight. The principal researcher is responsible for maintaining the methodological and ethical integrity of the study.

Bioethics, as a reflective discipline, must critically and constructively accompany the constant transformation of biomedical research. In the face of new challenges such as AI and gene editing, it is essential to promote an anticipatory ethics grounded in respect, precaution, and inclusion. Only in this way can a culture of trust and responsibility in the production of scientific knowledge be strengthened.

Ethical Considerations

This article corresponds to a narrative, documentary-type review grounded in a hermeneutic and deliberative bioethical approach. No human beings or animals were involved in the collection or analysis of data; therefore, approval by a research ethics committee was not required.

I declare that I have conflicts of interest related to the preparation, content, or publication of this manuscript. Compliance with the principles of academic integrity, transparency, and responsible citation of all sources used is guaranteed.

Likewise, the use of the ChatGPT tool (OpenAI) is declared solely as support for style review and text organization, with the author retaining full intellectual and academic responsibility for the content.

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