

Research with Human beings and its ethical aspects: integrative review

Geovana Christina Isidoro Bezerra¹, Emerson Alves Miguel Batista Barreto², Arnon Coelho Bezerra Filho³, Yago Ferreira Ferro⁴, Waldemar Naves do Amaral⁵

ABSTRACT

Objective: Analyze the ethical aspects of research with human beings.

Method and results: Integrative literature review, with 66 articles identified, using Academic Google and SciELO databases, from the following descriptors: ethics and research with humans, of which ten were selected for the study.

Conclusion: Research on human beings is essential for the development of science and medicine; however, they represent major challenges related to ethics. Guidelines are constantly improved to ensure safety, integrity and respect for the people who participate in research, but they have limited scope if not accompanied by the strengthening and improvement of ethics committees.

Keywords: Research with human beings; ethics

RESUMO

Pesquisas em seres humanos e seus aspectos éticos: revisão integrativa.

Objetivo: analisar os aspectos éticos das pesquisas em seres humanos.

Método e resultados: revisão integrativa de literatura, com identificação de 66 artigos usando os bancos de dados Google Acadêmico e SciELO, a partir dos descritores: ética e pesquisas em seres humanos, dos quais dez foram selecionados para o estudo.

Conclusão: As pesquisas em seres humanos são imprescindíveis para o desenvolvimento da ciência e da medicina, porém representam grandes desafios relacionados a ética. Diretrizes são aprimoradas constantemente com o intuito de garantir a segurança, a integridade e o respeito às pessoas que participam de pesquisas, porém apresentam alcance limitado se não forem acompanhadas de fortalecimento e aprimoramento dos comitês de ética.

Palavras-chave: Pesquisas em seres humanos; Ética.

1. **Medical intern**, Universidade de Gurupi (UnirG) – geovanachristinaisidorobezerra@gmail.com

2. **Medical intern**, Universidade de Gurupi (UnirG) – emersonambb@gmail.com

3. **Medical student**, Instituto Tocantinense Antônio Carlos Palmas (ITPAC) – arnoncbezerrafilho@gmail.com

4. **Doctor**, União das Faculdades dos Grandes Lagos (Unilago) – yagoferromed@gmail.com

5. **Professor and Director**, Faculdade de Medicina da Universidade Federal de Goiás – dr@waldemar.med.br

Mailing

Geovana Christina Isidoro Bezerra– Rua Alonso Valentim Cardoso Tavares – Limeira (SP), Brazil – CEP: 13480460

Introduction

There was a time when many researchers believed that their firm determination to do good, their integrity of character and their scientific rigor were enough to ensure the ethics of their research, nowadays this conception is no longer the object of consensus. The great development and increasing incorporation of new technologies in the field of health care; the greater diffusion of scientific knowledge through traditional media and, in particular, through the internet, as well as the expansion of social movements in defense of individual and collective rights, the discussion on ethics applied to health began to have philosophers, theologians, jurists, sociologists and, above all, citizens, whether as users of the system of health, or as subjects of scientific research.¹

Over the centuries, experiments with human beings have been carried out with different standards of quality and ethics. History reports several examples of the use of human beings in studies and research that shocked, and still shock humanity. In these cases, the absence of control mechanisms based on ethical and moral criteria resulted in abuse of experiments and in human beings being coerced.²

The ethical concern with research involving human beings presents the Nuremberg trials as a great landmark. On that occasion, criminals from the Second World War were tried, including some doctors who had been involved in or participated in torture disguised as research. In these experiments, human lives were sacrificed to know the limits of tolerance to extreme conditions, such as hypothermia, oxygen deficit and massive injection of pathogenic germs.³

From the horrors revealed in these trials, the Nuremberg Code was born, which also represents a historic rupture. Although this document was triggered by the events revealed, it does not refer to them, but to the conduct that a scientific researcher must follow. It is a show of wisdom that this first code of ethics in research avoided alluding to highly anomalous situations and preferred to focus on general ethical norms valid for all research. Even so, it is noteworthy that a trial of war criminals inspired a code of ethics in research.³

Despite the knowledge of the cruelties that took place in the concentration camps and the Nuremberg Code, research with human beings that violated fundamental ethical principles continued to be carried out. Consequently, the Declaration of Helsinki was created in 1964 in Finland, which is divided into: basic principles, medical research combined with professional care and non-therapeutic biomedical research involving human beings. This declaration addresses the need to comply with accepted scientific principles, as well as ethical and scientific review and good qualification of researchers when carrying out research with human beings. It places the need to provide and consent to information to the subject, assessment of risks/benefits, assuring study participants the best diagnostic and therapeutic methods available after the end of the research. And yet, it condemns the use of placebo when there is already an established effective treatment.⁴

In addition to the basic principles, there is Medical Research Combined with Professional Care, which determines, in the treatment of the sick person, the freedom of the physician to employ new therapeutic methods, if, in judgment, they offer hope of saving a life, restoring health or relieving suffering. Being a possible solution, and according to the patient's mental state, the doctor must obtain free consent, after having given a complete explanation. In case of legal incapacity, the consent obtained must be that of the legal guardian; which replaces that of the patient. The physician can only combine clinical research with professional care, provided that the objective represents the acquisition of a new medical discovery, as long as the clinical research is justified by its therapeutic value to the patient.⁵

The Declaration of Helsinki, over the decades, has undergone changes and additions to its principles, but none of them has undermined its originality in defending and protecting the human rights of people involved in clinical research.⁶

Method and results

This is an integrative literature review (IR) study, which synthesizes the available studies on a given topic and conducts practice based on scientific knowledge⁷. This type of review proposes the

following steps: formulation of a guiding question, search in the literature for studies related to the topic, categorization, evaluation, inclusion, interpretation, results and synthesis of the knowledge evidenced in the analyzed articles⁸. Thus, this study presents as a guiding question: “What are the ethical aspects of research on human beings?”

To carry out this study, the material already published on the topic was used as a guiding tool: books, scientific articles, periodicals and materials on the Internet available in the following databases: Latin American and Caribbean Health Sciences Literature (LILACS), International Literature on Health Sciences (MEDLINE) and Scientific Electronic Library Online (SCIELO). As a result of the search, 66 references were found, using the Boolean descriptors and operators: ethics in research in human beings. After this survey, repeated texts were excluded. At the end of the analysis, ten articles were considered eligible for the proposed study. After a thorough reading of each text, we tried to integrate the themes in order to achieve the objective proposed by this work.

TABLE 1 – RESEARCH.

ORDER	AUTHOR	TITLE
A1	Araújo LZS ⁹ .	Ethical aspects of scientific research.
A2	Amorim KPC ¹⁰ .	Research ethics in the Brazilian CEP-CONEP system: necessary reflections.
A3	Kottow M ³ .	History of ethics in research with human beings
A4	Veloso SCS, Cunha TR, Garrafa V ¹¹ .	Ethical control of research whose results pose a high risk to the health of the population.
A5	Schuch P, Victoria C ¹² .	Research involving human beings: reflections from Social Anthropology
A6	Ribeiro SAB, Ferreira SBL ¹³ .	Research involving human beings: research ethics committee
A7	Sardenberg T, Müller SS, Pereira HR, de Oliveira RA et al ¹⁴ .	Analysis of the ethical aspects of research on human beings contained in the Instructions to Authors of 139 Brazilian scientific journals
A8	Oliveira MLC ¹⁵ .	Ethics committees: research on human beings in Brazil
A9	Lima DF, Malacarne V ¹⁶ .	Ethics in research involving human beings: reflections from the experiences of UNIOESTE – science and education
A10	Bento LA ¹⁷ .	Bioethics and research in humans

Discussion

In modernity, scientific research is no longer the search for knowledge just for the sake of knowledge. It started to be thought of, above all, in terms of its practical and instrumental application.¹⁸ This paradigm has brought great advances in the areas of biology and life sciences. However, in addition to the intrinsic factors of science, there are several health, social, political and economic factors that influence the conduct of research, ranging from the choice of the object of study to the practical application of the results.¹⁹

In the same sense, Schramm considers that the advances achieved in the area of biotechnoscience are, at the same time, “[...] reasons for great hopes and anxieties, consensus and conflicts, in particular, of the moral type”.¹⁸

The advance of medicine towards the determination of new clinical and surgical treatments and new diagnostic methods involves experimentation in human beings. Tests on non-human animals, modern mathematical and statistical models, and intensive use of computers have not been able to exclude the final phase of experimenting on human beings.¹⁸

The use of human beings in scientific experiments brings undeniable benefits to society. However, there is always a conflict between the individual subjected to experimentation and science.²⁰

We must always remember that the purpose of research is to improve the health and well-being of patients and never cause harm or subject them to serious risk to achieve these goals.²¹

What stems from these considerations is the difficulty in determining the ideal threshold of compromise between scientific freedom and legitimate concerns for the safety and integrity of scientists, a conspiracy between science and business that turns against the protective bioethics of patients and participants.²¹

Currently, the biggest sponsor of clinical trials for the development of new drugs is the pharmaceutical industry. This segment consists of companies that follow the logic of the market. In this logic, it is necessary to see which activities give the most financial return, in order to invest and guarantee profits; a fact that, in most cases, is not in line with the priority needs of society. Angell warns “about the prudence of entrusting drug development to an industry whose responsibility lies entirely with investors, not the public (except in the narrow sense that drugs must be safe and effective)”.²²

Research ethics will have to face a topic that until now has been shyly avoided under the concept that science and economics do not mix, an idea that has already become completely obsolete. The contemporary engine of scientific activity is profit, the conquest of market niches, competitiveness and obtaining patents. Curiosity has been replaced by pragmatism, in a climate where researchers, sponsors and scientific institutions take care of their respective interests.³

A paradigmatic case is that of researcher Nancy Olivieri, who revealed negative data about the drug deferiprone, which she herself was studying, contrary to the interests and instructions of the sponsoring laboratory and her own university. Its ethical integrity was questioned by researchers who had no qualms about committing transgressions, doing improper and immoral science. This conflict can be summarized as the contrast between the values of science and the values of a large company. However, when the integrity of scientists fails, there is a conspiracy between science and business that turns against bioethics, which protects patients and participants.²³

Within this whole context, an indispensable reference is the Universal Declaration on Bioethics and Human Rights (UDBHR), whose objective is to balance the fulfillment of values such as human dignity, protection of vulnerabilities and scientific freedom, among others. In its Article 20, the aforementioned document points to the need for states to promote “the assessment and adequate management of risks related to medicine, life sciences and associated technologies”, while, in Article 24, it points out that : “States should promote the international dissemination of scientific information and encourage the free circulation and sharing of scientific and technological knowledge”. Among the principles presented by UDBHR, Article 4 - Benefit and Harm - can be highlighted, which points to the need to maximize direct and indirect benefits to patients, research subjects and other affected individuals, and any harm to them must be minimized. This indicates that, even when carrying out studies that do not involve the human being as an object, the risks and possible damages must be weighed against the expected benefits, not only for the subjects directly involved, but for the entire present and future population.²⁴

Brazil has a recognized system for the ethical evaluation of research involving human beings, linked to the National Health Council (CNS), constituted by the National Research Ethics Commission (CONEP) and by the various Research Ethics Committees (CEP) distributed by all regions of the country. This CEP-CONEP System was created by Resolution CNS 196/96.²⁵

Conclusion

The atrocities committed during the Second World War imposed the development of ethical norms for conducting research with human beings. Since Nuremberg (1947), various codes and resolutions have governed these practices around the world. In Brazil, Resolution 466/2012 of the National Health Council establishes the ethical and scientific foundations for this type of research.²⁶

The international guidelines on research ethics presented in this article should support the actions not only of researchers, but also of research sponsors and organizers. This is a way to

ensure the dignity of participants and to bring human rights closer to science. The steps for scientific research include moral consistency on the part of the research team, as well as requiring detailed reviews by the regulatory agencies of each country. The advancement of science has brought important achievements for people's well-being, but these gains in quality of life cannot be achieved at the expense of the dignity of research participants and the integrity of the scientific community.³

An ethically justifiable research needs to respect its participants in their dignity and autonomy, recognizing their vulnerability, assuring their willingness to contribute and remain, or not, in the research, through an express, free and informed expression; needs to balance risks and benefits, both known and potential, individual or collective, committing to maximum benefits and minimum harm and risk, ensuring that predictable harm will be avoided; it must have social relevance, which guarantees equal consideration of the interests involved, without losing the meaning of its socio-humanitarian purpose; and, finally, it needs to be previously approved by a research ethics committee (CEP).²⁷

It is therefore necessary that an ethical culture be encouraged and promoted in the area of research, in which those involved can recognize the challenges related to this process and have the sensitivity to act with equity, justice and respect, having as a guide the responsibility towards current and future generations. The intention is that ethical intentions turn into actions. However, for this to materialize, it is essential to focus on a critical and permanent evaluation and review of the CEP-CONEP System, as well as to provide it with sufficient human and material resources to deal with the complex challenges and, at the same time, value and account for the work of committee members within the institutions.²⁸

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Received on: 23/03/2022

Revisions required: 19/04/2022

Approved on: 16/05/2022
