

Ethics Principles in Oncology Research

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Citation: Petroianu A (2020) Ethics Principles in Oncology Research. *J Clin Oncol Ther*, Volume 2:1. 110. DOI: <https://doi.org/10.47275/2690-5663-110>.

Received: December 01, 2020; **Accepted:** December 11, 2020; **Published:** December 14, 2020

Commentary

According to Claude Bernard, “Physicians make therapeutic experiments daily on their patients, and surgeons practice everyday vivisections on their subjects whenever such a procedure can save someone’s life, cure his disease, or bring him a personal benefit” [1]. Despite being almost two centuries old, this thought remains current, since every physician is a researcher in her/his medical field, and Oncology is the area of Medicine with more published scientific works.

About 2500 years ago, when Western philosophy was structured in Greece, medical research and ethics were put together. The ethical principles associated with medical practice have been attributed to Hippocrates, knowing that this name is the image of many physicians who existed on the island of Kos [2]. A large part of these principles entered the tradition of medical citations, without discussion about their consistency and applicability in medical activities.

The most well-known Hippocratic principle is non-maleficence, “first not harm” [2]. It should be noted that in Oncology the only certainty in the treatment is the damage, always intending to obtain the benefit of a cure or relief, utilizing chemo-, radio- and immunotherapy associated with surgery. Every outcome is uncertain, and all medications have side effects. Thus, the desired benefit is only a probability. On the other hand, not causing harm means letting the disease progress with all its complications until death.

After the end of World War II, when the atrocities carried out by Germans and Japanese in the name of a pseudoscience were known, a serious limit on the medical research through codes of ethics became essential. Recommendations of medical ethics exist since the 18th century, but there was no obligation to respect them. The first relevant Code with laws to limit searches was established in the city that judged German war crimes and was named Nuremberg Code (1946) [3]. This document was improved by most of countries representatives in Finland and was called Declaration of Helsinki (1964). International ethics committees have revisited the Declaration of Helsinki every four years until 2020 for its updating, considering the evolution of scientific knowledge and social standards. This code is a reference for all committees of ethics in human research [4].

According to the Declaration of Helsinki, “the design and performance of each research study involving human subjects must be clearly described and justified in a research protocol” [4]. It should be

noted that each person has manifestations for each cancer, so strictly following a protocol without considering individual characteristics is dangerous. In contrast, if the protocols are not followed uniformly, it will be difficult to assess their beneficial and harmful results.

The Declaration of Helsinki recommends “the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention” [4]. Therefore the control group of patients who, according with the ethical principles of that document, do not receive adequate treatment, will have the progress of their disease, which in oncology represents progress towards sufferings and death.

Another statement of Declaration of Helsinki is “the research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins”, which seems to be obvious to protect the humans subjected to medical studies [4]. Only the protocol is carefully verified and approved, not the real study, which may be different from the assertions of the protocol. The ethics committees, which are extremely cautious with the paper data never verify the real experiment nor compare the data of the approved protocol with the method described in the published article related to the approved protocol, even knowing that the Declaration of Helsinki recommends them “having the right to monitor ongoing studies” [4]. All journals request the approved protocol, but none of them demands the approval of a “submitted a final report to the committee containing a summary of the study’s findings and conclusions” mentioned by the Declaration of Helsinki [4].

Another pivotal aspect included in the Declaration of Helsinki is “for a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative” [4]. Many times children, aged people and patients who are considered mentally incapables are not requested to agree to be submitted to an experiment and their authorized representatives sign the informed consent, including these not volunteers considered incapables in medical experiments. Who protects these pseudo-volunteers from their legally authorized representatives and the researchers of such studies?

Both the Nuremberg Code and the several Declarations of Helsinki state that “the experiment should be such as to yield fruitful results for the good of society” [3,4]. One might consider that the experiments carried out by Germans and Japanese in their concentration camps



were aimed to benefit society. What is the limit between criminal and ethically acceptable conduct? Very few people want to risk their lives for the good of society, even if they are volunteers.

The Declaration of Helsinki includes “appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured” [4]. Are the volunteers who accept to participate in a medical study only for financial needs appropriately compensated by the little payment for their involvement in the research? What is the compensation of soldiers who must follow their commanders’ requests? Is the reduction of the prison time an appropriate compensation for harmed experiments?

The Nüremberg code emphasizes “to terminate the experiment at any stage, if the experiment is likely to result in injury, disability, or death to the experimental subject and the risk cannot exceed the benefit and if the experiment causes damage, it must be stopped” and in the Declaration of Helsinki, “physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed” [3,4]. At the beginning of any therapeutic trial in humans, there is no data to establish its safety. Results obtained in animals are assumed for humans without guarantee. Only after following many volunteers during a long period of time, the risk of any treatment may be predictable. Even interrupting an experiment, the harm that occurred in the volunteers can be definitive and irreparable.

Both cited documents declare that “medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications” but they do not specify who determines the scientific and moral capacity of each researcher [3,4]. Every oncologist is qualified to carry out experiments on cancer patients, but few of them have enough scientific knowledge. On the other hand, researchers who do not have experience in managing cancer patients are not able to understand the dimension of all the physical and emotional effects of a new medical experiment [5,6].

The research in oncology is hardly limited by ethical principles.

Therefore, it is worth to remember the words of Immanuel Kant “the starry sky above me (no one and no law or principle can control who does not wish to respect) and the moral law within me” [7].

Acknowledgments

The author gratefully thanks the Research Support Foundation of the State of Minas Gerais (FAPEMIG), the National Council for Scientific and Technological Development (CNPq) and the Dean’s Office for Research (Pró-reitoria de Pesquisa) at UFMG for their financial support.

Conflict of Interests Statement

The author declares no conflict or competing interest with respect to the authorship and publication of this article. The author has no financial relationship with any organization.

Disclosure of Funding Support

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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