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Maria Rita Carvalho Garbi Novaes & Dirce Bellezi Guilhem

Bioethics emerged amidst major social transformations, significant advances in scientific knowledge and questions related to access and distribution of resources for health care. Bioethics is considered to be an applied form of ethics because it favors reflection and proposes alternatives for the resolution of conflicts that emerge from life in society and its interrelationship with the environment. It was created as a bridge to unite the life sciences and respect for humanistic issues and moral values. It represents the systematic study of human conduct in the process of health care in the light of moral values and principles. It goes beyond daily practice and contemplates the implications of technology and its consequences for future generations. In this context, Bioethics is comprehensive, inclusive, pluralistic and multiprofessional, allowing an extended view on the ethics that underlies the exercise of different health professions¹.

Bioethical principles such as justice, beneficence, non-maleficence, autonomy are taken as references, in addition to equity, public and private responsibility, solidarity and prudence, among others. These principles seek to achieve respect for values such as free will, the exercise of citizenship with conscience, respect for the dignity of the human being and the process of decision-making in the scenarios where health care and scientific practices involving human beings are performed. Such research should be developed taking into account adherence to human rights and good technical, ethical and scientific practices².

One of the aspects required for the formulation, realization and dissemination of research results is the observance of ethical requirements and appropriate conduct for the preservation of scientific integrity at all stages of the development of the study and dissemination of results through the publication of reports, articles and other forms of scientific dissemination³.

These include adherence to behaviors and values that seek the impartiality of the researcher during the development of the research, the legitimacy of the data and results used, the correct establishment of authorship and co-authorship, compliance with the regulated copyright, attention to the vulnerability of research participants, also considering the dignity of the human person, the risks and the benefits to actors involved. In addition, it is important that there is no conflict of interest between researchers, funders, and study participants in the sense of not impairing the impartiality of the project⁴.

These aspects were addressed by Resolution nº 466 of the National Health Council (NHC) of December 12, 2012⁵, published on June 13, 2013 and which revoked Resolution NHC nº 196/1996⁶. This resolution deals with guidelines and regulatory norms of research involving human beings and it should cover research from all areas of knowledge, including health and human sciences. In practice, it is applied mainly to biomedical research, not covering the methodological specificities of other areas, particularly of researches with qualitative delineations.

In order to meet the demand from the areas of social and human sciences and after intense activity of the group formed for this purpose, NHC Resolution no 510/2016 was published on the ethical specificities of these researches and other areas that use these methodological designs⁷. This was the first Brazilian norm focused specifically on these areas and represents a milestone in research ethics in the country. The norm is aimed at protecting the human rights of participants of the studies.

Complementing the resolutions created by the NHC, there are some laws, such as Law nº 11,105 of March 24, 2005, which deals with biosafety and has as one of its preponderant aspects the regulation of activities involving genetically modified organisms - GMOs and their derivatives⁸. In turn, Law 9.610/1998 protects the author's rights on intellectual works, independent of registration, and includes scientific texts as an object of protection in its 7th article⁹. In scientific practice, legislation and ethics must act in an interconnected manner. The distinction between these two spheres comes from their applicability: the law must be observed and it brings sanctions in case of noncompliance, while ethical guidelines are infra-legal rules but they take on public authority because they achieve legitimacy in the context of their use. The Professional Codes of Ethics are subject to the transparency and validity of the actions. These documents are tangible provided they are regulated by a Federal Professional Council capable of applying sanctions for noncompliance with ethical norms, ranging from warnings to prohibition of the legal professional practice.

The concern to ensure that ethical and legal aspects are observed in science led the National Council for Scientific and Technological Development (CNPq), one of the main development agencies in Brazil, to prepare and disseminate in 2011 a report containing guidelines on good scientific practice. This document includes measures to curb plagiarism, self-plagiarism, improper inclusion of co-authorship

and manipulation of information and results¹⁰. These aspects should be highlighted in view of the increase in cases of retraction of articles published in scientific journals due to fraud and violation of rights. Notably, the latter is a crime foreseen in article 184 of the Brazilian Penal Code¹¹.

Care to make science with quality and integrity, led the country to host the 4th World Conference on Scientific Integrity in 2015,¹² and the 4th Brazilian Meeting on Integrity in Research and Ethics in Science and Publications (BRISPE) in 2016.¹³ It should be emphasized, however, that scientific research indicators count the number of articles published and the number of citations, but not the quality of the works. This is therefore a favorable scenario for the production of articles in series in institutions that offer graduate, master and doctoral courses, without the proper rigor of scientific integrity¹³.

In this context, it is observed that ethics in research involving human beings is extremely relevant, especially with respect to vulnerable individuals or groups. Vulnerability is characterized as a condition of people or groups with reduced power of choice or even those in which have no influence and are disregarded in the decision making process, a fact that has several possible causes. These people are susceptible due to the difficulty of resisting the decisions of third parties, legally indicated as responsible¹⁴.

Although these persons are aware and able to make choices, it is necessary to minimize their vulnerability by proving that they understood the issues involved in their participation in the research. It is essential that effective consent is provided for inclusion in the study. It is evident that the mere signing of a form is not an indication that the potential participant understood the information or effectively consented to carry out the procedures. It is necessary to guarantee the recognition of the autonomy and dignity of the subjects¹⁴.

The creation and dissemination of international guidelines - such as the Nuremberg Code, the Helsinki Declaration, the Belmont Report, the Universal Declaration on Bioethics and Human Rights (DUBDH) - and the Brazilian regulatory framework on research involving human beings represent only the initial step to adopt principles that should subsidize the scientific practice in Brazil. It is recognized that a broad approach to ethical values required in the context of social, biomedical and clinical research contributes to reinforcing principles of equity and respect for human subjects, considering their position in relation to the decision-making process regarding whether or not to participate in an experiment or any other type of study.

It should be noted that the discussions taken during the Nuremberg Trial on ethical principles in research involving human beings that occurred over the last 60 years have not been able to resolve issues related to the different degrees of protection that should be directed to study volunteers, especially in situations of social, biological, cognitive and cultural vulnerability. Responsibility in this scenario should be shared among researchers, research ethics committees, teaching and research institutions, development agencies, sponsors, and society in general, as an instance of control of scientific practice. In other words, on the one hand it is necessary to broaden the debate and include new voices and perspectives on an extremely complex issue that raises questions, and on the other hand, to ensure respect for the dignity of the human beings included in the research.

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