



Ethical aspects of nursing research

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With the advances of nursing scientific production in recent decades, in tandem with the growth of nursing postgraduate programs in Brazil, the discussion about ethics in research with human beings is perennial and relevant to nursing research.

With its foundation in care, nursing has already discussed issues related to ethics and bioethics in the approach of dilemmas of the daily work process (assistance, management, teaching and research), moral principles, reference to the code of professional ethics, the rights and the obligations in health care and patients' rights⁽¹⁾.

Concerning research, the approach about the social responsibility of studies, the quality and relevance of findings, the risks related to moral exposure of the subjects, the use of new treatments and care technologies have increased. These themes are highlighted due to an expansion on the use of different research designs in the nursing area, both in the qualitative and quantitative approaches⁽²⁾. It implies a constant observation of bioethics principles, such as autonomy, nonmaleficence, beneficence, justice and equity.

As for regulations dealing specifically with research ethics, the *Conselho Nacional em Saúde* [National Health Council] implemented the resolution 466 from December 12, 2012, which revokes Resolution 196/96. This new resolution has a more philosophical text, based on the principles of autonomy and human dignity, and it also brings new concepts and modifications to some ethical issues that deserve attention from researchers.

When comparing the previous resolution⁽³⁾ with the current one⁽⁴⁾, it is immediately noticed that it brings recent international documents, such as the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the Universal Declaration on Bioethics and Human Rights (2004), which are reflections of scientific advances.

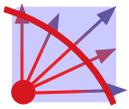
With regard to the terms and definitions, the Resolution 466/2012 incorporated important changes, such as changing the term subject of the research to participant of the research and the inclusion of concepts such as free and informed consent, holistic care, immediate care and benefits of the research. Still, the term sponsor received a new definition, in which the proponent and co-participant organizations may be considered as sponsors depending on the support given to research.

In the section that deals with ethical aspects, there was a change related to the participants' access to the benefits of the research, which started to be for indefinite time. It was still included for women who declared not having the risk of getting pregnant, the guarantee to the right of participating in the research without the mandatory use of contraceptives.

The current resolution highlights the need to follow strictly the steps of the informed and free consent process. As it considers that research with human beings involves risks of different types and gradations, the ethical analysis of this component is essential. As for the research protocol, the list of required documents was removed, replaced by the information that the *Plataforma Brasil* [Brazil Platform] is the official system to launch research for analysis and monitoring.

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The analysis of this resolution and the discussion about its modifications and peculiarities must be present in the scientific community, among all those involved in research with human beings. Thus, the submission of a research project to the assessment of the Research Ethics Committee should not be seen merely as a bureaucratic step of the research process, but as the opportunity to identify and correct ethical problems likely to compromise the potential benefits sought in the study.

It is noteworthy that Rev Rene aims at ensuring the ethical quality of articles published when it requests an opinion with the approval of the Research Ethics Committee system of research involving human beings and conducted in Brazil. And in the case of research conducted abroad, there is a requirement to fulfill the specific laws of the country where it was performed.

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