

Seven Ethical Requirements for Quantitative and Qualitative Research in Nursing: Experiences of Three Research Ethics Committees from Santiago, Chile

Irene Acevedo Pérez

Registered Nurse
Master of Science in Bioethics
President of the Scientific Ethics Committee
Faculty of Infirmery
Universidad Andrés Bello
Teacher at the Faculty of Infirmery
Universidad Andrés Bello
Teacher at the Faculty of Health Sciences
Universidad Diego Portales

María Eugenia Rapiman

Registered Nurse
Master's Degree in Psychology
Graduate Diploma in Bioethics
Member of the Research Ethics Committee
Faculty of Medicine at Universidad Diego Portales
Teacher at the Faculty of Health Sciences
Universidad Diego Portales

Marianella Cáneo Orellana

Registered Nurse Midwife
Graduate Diploma in Bioethics
Vice-President at the Scientific Ethics Committee
Universidad Andrés Bello
Teacher at the Faculty of Medicine
Universidad Diego Portales

Laura Rueda Castro

Registered Occupational Therapy
Master of Science in Bioethics
President of the Scientific Ethics Committee
CESFAM Cristo Vive
Teacher at the Faculty of Medicine
Universidad de Chile

Abstract

Scientific research is one of the tools that strengthen the nursing discipline by generating new knowledge, which provides theoretical support and contributes the necessary evidence to improve nursing care performance of health professionals in all their practical and theoretical activities. Subsequent to the historical events related with research on human beings performed during the 20th century, in which researchers favored the search of new knowledge and were particularly concerned with achieving their scientific successes rather than taking care of the well-being of the individual study patient, brought about the first laws, codes and a bill of rights to regulate research from an ethical point of view. Their purpose was to avoid actions or situations which could attempt against the basic principles of respect to the human dignity.

Today, when carrying out a research project it is not only necessary to rigorously apply each one of the steps of the scientific method, but also to comply thoroughly with the ethical aspects. In that context, the concerns regarding the ethical aspects involved in research on human beings demand the review of the principles and requirements that such investigations must comply with in order to be considered ethical. The present document intends to analyze the seven ethical requirements proposed by Ezekiel Emanuel to quantitative studies also to qualitative research paradigms. His requirements should be taken into account by the nursing professional when planning and carrying out a research project during undergraduate, graduate or certification programs, as well as members of research ethics committees that review and approve research projects.

Historical background of ethics regulations

The advancements in medicine are contributing to a great number of benefits for healthy or sick people but, on the other hand, investigations in this field have led to the development of various ethical dilemmas resulting, on certain occasions, of not complying with established rules, codes, or regulations of scientific research. While it is true that research on human beings should have as a purpose of contributing to the improvement of diagnostic and prophylactic procedures, and also to the understanding of the etiology and pathogenesis of a disease, with the goal of generating knowledge to ameliorate the quality of health care, it is nevertheless also true that these studies should be thoroughly reviewed to protect the rights of participants and, specially, of the vulnerable populations, in order to avoid a violation of their dignity.

At the present time, the primary requirement before starting any research involving human participants includes the ethical considerations. This demand is underpinned by historical events related to research on human beings carried out during the 20th century, where researchers favored the search of new knowledge more concerned with the achievement of their scientific successes rather than in the well-being of the individual. The first laws to regulate clinical research arose in 1931, the German Law. In 1947, the excesses of the Nazi period led to the drafting of the Nuremberg Code consisting of ethical rules about experimentation on human beings, which attempted to reconcile medical research and ethics. The Nuremberg Code emphasized the importance of voluntary, informed consent of people undergoing an experiment (without any kind of coercion), the need to avoid any unnecessary physical or mental suffering to the participant, and to provide evidence that the experiment is necessary and will entail a benefit for the whole society(1). The aspects not covered in this code were the inclusion of people with limitations to give their informed consent and the independent assessment of the research.

The Nuremberg principles were later reviewed and enriched in the Declaration of Helsinki created in 1964 by the World Medical Association, which has been revised seven times (last review 2013). Relevant aspects of this international rule include the review of research protocols by Ethics Committees (1975), as well as a regulation of the use of placebo in clinical trials (1996), and guarantees of continuity of treatment (2000). However, between the 40s and the 70s and even after the publication of the Nuremberg Code and the first versions of the Declaration of Helsinki, such studies as the Tuskegee study, Willowbrook or Brooklyn were conducted, as well as various experiments with radioactive material. Two of the latter were disclosed in "The Human Radiation Experiments: Final Report of the President's Advisory Committee" delivered to President Clinton in 1996 (2) as actions which had infringed the rights of autonomy, security and dignity of the participants. Thus, in 1974, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created by means of a mandate of the United States Congress, whose purpose was to develop a proposal for a method of analysis and ethical assessment of research projects. It identified the basic ethical principles that should guide the biomedical research involving human participants. Three Principles were defined: Respect for people, Beneficence and Non-maleficence, and Justice.

In 1982, the Council for International Organization of Medical Sciences (CIOMS), together with the World Health Organization (WHO), developed the "International Guidelines Proposed for Biomedical Research on Human Beings". These guidelines aimed to present an effective method for the application of ethical principles contained in the Nuremberg Code and in the Declaration of Helsinki for the protection of specific communities or populations and not only to protect isolated individuals in developing countries. In the year 2000, Ezekiel Emanuel accurately summarized the existing documents establishing the ethical requirements of biomedical research, stating seven conditions that must be complied with in order for the research to be ethically correct: social value, scientific validity, equitable selection of subjects, favorable risk/benefit ratio, informed consent, respect for subjects and independent assessment.

(Ethics Committee).(3) While it is true that Ezekiel Emanuel defines that these requirements must be applied in all clinical trials because of the higher risk for subjects in experimental studies with an intervention, it is nevertheless true that they should also be implemented on qualitative research paradigms on human subjects. The latter are widely used in undergraduate, graduate, or certification programs in the nursing discipline. The present document intends to analyze these seven ethical requirements in qualitative, quantitative and in research which uses both paradigms.

Research in Nursing

Scientific research is necessary for the progress of medicine and is one of the tools that strengthen the nursing discipline by providing theoretical knowledge to support the selection of the type of care that health professionals must supply in any of their practical or theoretical activities. Including the latest research results raises the quality of the professional and can lead to a positive acknowledgement by our peers and other professionals integrating the health care team. But its most important contribution is that it enables the generation of evidence on which clinical practice should be based on, thus allowing to improve the quality of care provided to healthy or sick people, who are the central entity of our professional activity in nursing. Scientific research can be conceptualized in three ways: as a process, as a procedure or as a product. The process or method has a key methodological question that starts the process and conducts the research through procedures to provide a concrete and final product (the publication). The questions that an ethical evaluation should include are the following for who is the research of interest? Is the promotion of knowledge most important and the people only means to achieve an objective? Does the objective of the research bring direct or indirect benefits involving the preference of the patients? Or, does the interest focus on social, dynamic, economic, or community interests and people are mere informants? There are two paradigms which can be used for carrying out research. On the one hand, there are studies conducted under the quantitative paradigm whose foundation is logical positivism and empiricism, its nature is objective, static, tangible, and convergent and its purpose is to explain, infer, control the phenomena and verify theories. It seeks to establish empirical generalizations and to present reproducible and reliable results.

On the other hand, there are qualitative investigations with phenomenological basis, interpretative, with a multiple dynamic nature, holistic, divergent and whose purpose is to understand and interpret the meaning of experiences, intentions and actions of people, using mainly in its analysis the language of words and the inductive observation. This type of study represents minimal risk to participants but may in some occasions involve greater risks as in experimental researches when it comes to studies dealing with psychiatric pathologies, drug consumption, abuse, or vulnerability situations of participants. The qualitative research approach provides new possibilities for understanding the phenomena of social interest from the scientific point of view. The qualitative research can be seen as the attempt to obtain a thorough comprehension of the meanings and definitions that people give us, rather than the production of a quantitative measure of their characteristics or behavior (4) This approach sometimes helps to complement the existing knowledge regarding health problems that have been impossible to resolve from positivism and could be explained through the understanding of human behavior.

Requirements for ethical research

The World Medical Association Declaration of Helsinki (Tokyo 2004) describes the research in the following terms: “A systematic, organized and objective process, whose purpose is to respond to a question or hypothesis to broaden the knowledge and information about something unknown“. The research allows us to approach science from several perspectives. It is possible that our goal is to respond clearly and accurately to a problem or try to understand a situation involved in such problem. Ezekiel Emanuel proposes seven requirements that a clinical research should comply with to be ethical. We believe that they should not only be required in quantitative, but also in qualitative studies and that all research on human beings must comply with them. In the following we review the seven requirements including an application to the qualitative research.

1. Social value

This requirement states that any research proposal should be of social, scientific, or clinical interest, and point out the contribution that the expected results will provide to the knowledge of the nursing discipline, health or well-being of people, or to the understanding of unresolved health problems that could generate health care improvement proposals.

The value of a study also considers its originality: the body of the knowledge that motivates to conduct a research is a relevant aspect to highlight, being necessary the presentation of a state of the art implying the accomplishment of an accurately and updated bibliographic search with scientific articles of high impact and specifying bibliographic references according to international rules. This will justify the knowledge gap related to the research question posed or the need for further studies if it is a topic that has not been accurately investigated. It aims to prevent exploiting the participants to the study, considering their possibly vulnerable conditions and not expose them to potential risks and harms. Value also implies that the researchers should have the necessary skills and knowledge on the studied topic and their experience as researcher should be accredited by a corresponding curriculum.

2. Scientific validity

The research must follow every single step of the scientific method to ensure the methodological rigor in each type of research, especially in those involving human beings. A badly designed research project, which does not comply with coherence and methodological rigor to respond a research question, lacking of internal and external validity, will produce unreliable and non-applicable results. This implies the use of human resources and material without the achievement of the goal that led to conduct the study, having implications in the respect towards the participants, as well as to all levels involved in the research. Then, the question is how is the scientific rigor ensured? Every research starts with a Research Question (RQ) to indicate the paradigm to be followed and the appropriate design to answer this question. The methodological rigor assures the internal validity of the study that certifies reliable and extrapolates table results. In the quantitative paradigm, the internal validity is justified by the correct selection of the subjects participants to be studied, with a study population defined by precise selection criteria, with a description of how the sample size calculation was done and of the sampling technique for the inclusion of the subjects of the study. The purpose of this is to avoid selection bias. It is also necessary to define the correct variables to be measured in order to answer to the RQ. Measurements must be valid and reliable using the appropriate instruments. Furthermore, in clinical trials the blinding technique of the treatment assignment and the description of the randomization process must be clearly established. Finally, the statistical strategy of the analysis of results must be properly defined.

In qualitative research, the design refers to the general approach used in the research process, which- in comparison to quantitative research -is more flexible and open, and where the course of action is ruled by the field of research (participants and evolution of the events). Thus, the design is adapted to the conditions of the scenario or environment. (4) Although the selection of the appropriate design in qualitative research is also important, there is not a clear division between them when carrying out the research and it can comprise elements of different designs. The criteria used to assess the methodological rigor are: dependency, credibility, adaptability and transferability Guba & Lincoln 1989. By dependency or logical consistency, one describes the degree of equivalence between results obtained from the present study compared with the analysis of similar data gathered in the field by other researchers. It assesses the accuracy of the measurements.(4) Credibility refers to how true the obtained results are from the perspective of the participants of the study and for other people that have been in contact to the studied phenomenon. It assesses the validity of the measurements. (4) The audit ability corresponds to the possibility that other investigators would have to review the data and reach equal or similar conclusions. This assesses both the reliability of measurements and the transferability or applicability of the results to other populations.(4) Hence, a rigorous methodological design is directly proportional to the scientific validity of the research as well as to the validity of the results obtained which compel to publish them.

3. Equitable selection of participants

One of the important aspects of scientific research methodology is the selection criteria of the participants. The quantitative methodology applies different types of sampling depending on the purpose and nature of the study. The most relevant feature is the implementation and protection of equity and justice when defining the type of sample selection so that all individuals who comply with the selection criteria have an equal possibility to participate in the study. For example, clinical trials where new drugs are tested should not only include individuals belonging to vulnerable socio-economic populations. Instead, the studied sample should include participants from different socioeconomic strata who comply with the selection criteria. In a qualitative study this requirement does not apply because the sample is chosen according to the inclusion and exclusion criteria and to the saturation of the responses obtained.

It is also important to bear in mind the condition of vulnerability of the participants and to safeguard equity and justice for all of them. All the participants should receive the same benefits. Another important aspect to consider is that there should not be any incentives to encourage participating, especially granted to the poorest and most marginalized communities which could favor a group over the implementation of the established inclusion and exclusion criteria. There should not exist favored and not favored groups. Thus, the concept of distributive justice fully applies to this requirement.

4. Favorable risk-benefit ratio

The fulfillment of this requirement must assure risk reduction for participants and that the risk should be minimal in relation to the benefits they will obtain. In scientific research, the golden rule that refers to the minimum risk versus the greater benefit governs. When applying this theoretical balance, one must control that the benefits are always greater and favors the largest feasible number of people, and if there are risks, these should be minimal. The participants must know the benefits and risks which must be clearly stated in the document of informed consent. Many times the risks of participation are minimized or hidden to the participant as this information would reduce the number of them; the researcher must be prepared and avoid this situation.

5. Independent Assessment

Each research project must be reviewed by a group of experts called the Independent Ethics Committee before its start-up. This Committee is appointed to review the appropriateness of a study protocol in a neutral, objective manner and must not have any conflict of interest related to it. It should have internal rules to safeguard possible conflicts of interest as for example to carry out the review of research protocols by means of a blind assessment where the primary aspect to be assessed is the research proposal and not the curriculum or prestige of the researchers. All Independent Scientific Ethics Committee should be accredited by a competent institution and be recognized by a government agency to comply with the organizational and functional regulations regarding ethical and scientific aspects when reviewing research projects.

6. Informed Consent

In each research project, a document must be drafted that clearly identifies the title, origin, research purpose, procedures to be carried out, risks and benefits for participants, how risks would be handled and, if needed, who pays the expenses incurred. This document must explicitly mention the freedom to participate or not in the research and the right to withdraw from it at any time without any consequences. Further, it must explicitly mention how the confidentiality of the information obtained will be protected. In addition, this document must be validated in a population with similar characteristics to the study group prior to its implementation, in order to ensure the clarity of the message. One must remember that the informed consent process constitutes an exercise of the principle of autonomy, and must be carried out free of persuasion, manipulation, and coercion. The document must be clear, precise and understandable for the population where it will be applied. In its first section it must contain all the necessary information to enable a good decision of the participant and in the second section it must include the participant's statement with a detailed explanation of what he/she has received as information.

7. Respect of research participants

It is important to respect the dignity of the study participants and it is essential to bear in mind the possible condition of vulnerability of some of them and to safeguard the confidentiality during the whole research process including the research presentation in scientific events and publishing of the obtained results. The obtained data should be encoded in order to maintain, anonymity and document that might identify participants. This requirement of anonymity must also be considered when publishing research results and every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information, including the storage of the research documents in a safe place.

Conclusions

The requirement that research projects be subjected to a rigorous ethical evaluation by a Scientific Ethics Committee, regardless of the origin of such projects: academic, health care, commercial or other, responds to the need to protect the rights of any individual involved in an investigation. To be able to perform the evaluation, it is important that some of the Ethics Committee members have the appropriate qualifications in bioethics and experience in the methodology applied to different types of research paradigms.

Ethical aspects and the internal validity of a scientific study cannot be assessed if the knowledge that is required in terms of methodology and ethical research is not available or is inaccurate. It is not enough to be a health care professional or even a researcher with great enthusiasm! The formation and regulation of ethical committees are defined in different legislations. However, if not both the methodological aspects together with ethical requirements are not considered, the ethical assessment proposed by Ezekiel Emanuel would only become a fallacy.

References

- Sierra X. Ethics and medical research in humans: A historical perspective. *Dermo-Sifiliográficas Records* 2011; 102(6):395—401
- Lemmens T. In the Name of National Security: lessons from the final report on human radiation experiments. *European Journal of Health Law*, 1999; 6:7-23
- Emanuel E J. What makes clinical research ethical? *JAMA* 2000; 283: 2701-11.
- Salgado Levano, Ana Cecilia. Qualitative research: designs, evaluation of methodological rigor and challenges. *Liber*. [Online]. 2007, vol.13, n.13 [citado 2016-10-17], pp. 71-78. Disponible en: <http://www.scielo.org.pe/scielo.php?script=sci_arttext&pid=S1729-48272007000100009&lng=es&nrm=iso>. ISSN 1729-4827
- Rodríguez E. Committees of ethical and scientific evaluation for the investigation in human beings and the guidelines CIOMS 2002 (2004) *Acta bioethica. Versión On-line* ISSN 1726-569X Law of investigation 20.120 (2010). MINSAL Chile. www.minsal.cl
- Acevedo, Irene. Aspects ethics in research. *Science and nursing. Iberoamerican Journal of Research* .8:15-18. 2002