Characterization of risks in search of an ethics committee in research protocols: bioethical analysis

Camila Maria Pereira Rates [1], *Marcella Rodrigues e Costa* [2], *Juliana Dias Reis Pessalacia* [3]

Abstract

A descriptive study in order to learn how researchers described risks and protective/preventive measures of their researches submitted to analyzes by an ethics committee in research. 175 research protocols submitted to a research ethics committee were included. As a result, only 38 (24.7%) described the risks in the forms and 36 (23.5%) in the informed consent. However, 110 (62.9%) described preventive measures in the forms and 143 (93.5%) in the informed consent. It was concluded that, although researchers have identified preventive measures, they have not described the risks to which the measures were targeted. It is possible that they find it hard to describe risks since they relate them to injuries.

Keywords: Ethical review committee. Ethics in research. Protocols. Bioethics.

Resumo

Caracterização de riscos em protocolos submetidos a um comitê de ética em pesquisa: análise bioética

Estudo descritivo realizado com o objetivo de identificar como os pesquisadores descreveram os riscos e as medidas de proteção/prevenção de suas pesquisas submetidas à análise por um comitê de ética em pesquisa. Foram incluídos 175 protocolos de pesquisa de um comitê de ética em pesquisa da cidade de Divinópolis, Minas Gerais. Como resultado, encontrou-se que somente 38 (24,7%) pesquisadores descreveram os riscos nos formulários e 36 (23,5%) no termo de consentimento. Entretanto, 110 (62,9%) descreveram as medidas de prevenção nos formulários e 143 (93,5%) as descreveram no termo de consentimento. Concluiu-se que, embora os pesquisadores tenham identificado as medidas de prevenção, não descreveram quais seriam propriamente os riscos de suas pesquisas. É possível que tenham certa dificuldade em descrever os riscos por associá-los a danos.

Palavras-chave: Comitê de revisão ética. Ética em pesquisa. Protocolos. Bioética.

Resumen

Caracterización de los riesgos en los protocolos sometidos a un comité de ética en investigación: análisis bioético

Estudio descriptivo con el fin de conocer cómo los investigadores describieron los riesgos y las medidas de protección/prevención de sus investigaciones sometidas a análisis por un comité de ética en investigación. Se evaluaron 175 protocolos de investigación de un comité de ética en investigación de la ciudad de Divinópolis, Minas Gerais. Como resultado sólo 38 (24,7%) de los investigadores describieron los riesgos en los formularios y 36 (23,5%) en el término de consentimiento informado. Sin embargo, 110 (62,9%) describieron las medidas de prevención en los formularios y 143 (93,5%) en el término de consentimiento informado. Se concluye que aunque los investigadores han identificado las medidas de prevención, no describieron exactamente cuáles son los riesgos de sus investigaciones. Es posible que tengan alguna dificultad en la descripción de los riesgos por asociarlos a daños.

Palabras-clave: Comité de revisión ética. Ética en la investigación. Protocolos. Bioética.

Aprovação CEP Hospital São João de Deus 183/11

1. Mestranda camila.rates@yahoo.com.br **2. Graduanda** marcella_nany@hotmail.com **3. Doutora** juliana@pessalacia.com.br – Universidade Federal de São João Del Rei (UFSJ), Campus Centro-Oeste Dona Lindu, Divinópolis/MG, Brasil.

Correspondência
Juliana Dias Reis Pessalacia – Rua São Paulo, 1.710/104 Santo Antônio CEP 35502-025. Divinópolis/MG, Brasil.

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Research article

Researches conducted by health professionals often involve the participation of human beings, a fact that makes it essential to assess the research project by an independent ethics committee before its implementation. The ethical evaluation by the Research Ethics Committee (CEP, acronym in Portuguese) with humans provides that a research will only be justifiable if its benefits overwhelm its risks and there is no imminent risk of death or disability for participants subject. In addition, one should establish measures to prevent or minimize the risks identified in the survey.

The Resolution 466/12, approved by the National Health Council (CNS, acronym in Portuguese) of the Ministry of Health (MOH) said that all research with humans involves risks which must be predicted and described in the research protocol to be evaluated by the CEP. It also defines, in its section II-22: *Research risk: the possibility of injury to the physical, mental, moral, intellectual, social, cultural or spiritual human being at any stage of an investigation or resulted from it* [1].

Thus, it is important that the researcher has ethical awareness and is able to make a critical analysis of the risks of his research. It is understood that ethics is meant to reflect on human actions and their purpose in order to understand the criteria and values that guide the judgment of the action in its various activities [2].

Bioethics - field that can aid decision making, as well as the reflection about the risks of a survey - can be defined as the systematic study of human activity in the area of life sciences and health care, to the extent that this conduct is examined in the light of moral values and principles [3]. The bioethics is an attempt to grasp and understand the true meaning of new, enabling us to a probable adaptation [4].

Just like any human activity, the survey contains various ethical dimensions [5]. The term "research" relates to a class of activities designed to develop or contribute to generalizable knowledge, which consists of theories, principles or relationships [6]. In large part of contemporary democratic countries, there is a perception that all research conducted in any area of knowledge, and with human beings as objects of research, should be reviewed in the epistemological, methodological and ethical contexts, by their peers and by society through a competent and recognized instance [7].

The idea of necessity of experiments control to ensure the welfare of the participants came up with the Nuremberg Code of 1947, which determines the need for voluntary consent of the individuals involved in the research, after its due clarification of the objectives and risks the project. This document influenced the creation by the World Medical Association (AMA, acronym in Portuguese) in 1964, of the Declaration of Helsinki, which refines and strengthens ethical parameters to studies conducted by medical professionals. This statement was modified between the 1970s and 1990s. In 1975, it was incorporated a requirement for prior approval of any research project on human beings by a CEP [8].

In Brazil, since 1988 the CNS had already resolved by the formation of CEP to human studies by Resolution 01/88, an important milestone in the path of formalization of research ethics in the health field. This resolution was revised in 1995, when the public bioethics was born, responsible for the challenge of facing new health issues that consolidate throughout the last decade of the twentieth century. Among many other functions, the CNS fit a new role: the monitoring of the development process and scientific and technological incorporation in the health area. Thus arose the Resolution 196 of October 16th, 1996, establishing the system CEP/ National Committee for Ethics in Research (Conep) for evaluation of research involving human subjects, which, in addition to the local CEP, now has Conep for analysis of specific types of studies. The System CEP/Conep was a mirrored process which included, with high degree of detail, the ethical requirements aimed at guiding research in the health field [9]. The Resolution 196/96 was reviewed and originated Resolution 466/12, standard currently in force that keeps many points the previous resolution.

One of the requirements set forth in Resolution 196/96, and maintained in Resolution 466/12, refers to the free and informed consent (IC). It is the approval given by the subject and / or his legal representative, after full explanation of the nature of the research, its objectives, methods, anticipated benefits, potential risks and the discomfort it may cause, set in a consent form, authorizing their voluntary participation in the survey [10]. The norm considers that potentially every experiment can cause permanent damage or any physical, psychological, social, moral, intellectual, cultural, spiritual and economic nature [6]. Hence, the present study aimed to identify how the researchers described the risks and protective measures/prevention of their submitted researches to analysis by a CEP.

Methods

It was a descriptive and exploratory study, conducted from the collection of pre-existing data in a CEP with human subjects from a philanthropic hospital in Divinópolis, Minas Gerais, Brazil. It is a CEP registered in the Conep, which since 2005 holds monthly meetings to analyze its projects. To collect data, we used a script containing closed questions about the characterization of the research, risks and protective measures, being therefore defined *a priori* categories of the study. This script was developed by the own researchers based on data found in the literature on the subject.

The study included all research protocols of the researchers who submitted their projects to the CEP, from March 2006 to March 2011, regardless of its final opinion, that is, if approved, not approved or pending. It must be said that illegible and/or incomplete information protocols were excluded. Thus, the final sample consisted of 175 protocols.

Data were arranged in a database created in Microsoft Excel and then analyzed using simple descriptive statistics. To preserve the ethical aspects of research with human subjects, the provisions of Resolution 466/12 were submitted and before the data collection, the research project was analyzed by the CEP of the research institution.

Results and discussion

On the professional category of the researchers, it was observed that 75 (42.3%) were nurses; 58 (33.2%), physicians; 12 (6.9%), physical therapists; 10 (5.7%), pharmaceuticals; 8 (4.6%), biologists; and 12 (7.3%), other professionals. The predominance of nurses among the researchers who submitted their research protocols to CEP may be related to the current increase in research in nursing. In addition, there recently is a considerable increase in divulgation of research made by nurses [11].

Regarding the institutional affiliation of the researchers, it was found that the majority, that is, 96 (54.9%), works in universities; 57 (32.5%) in hospitals; 15 (8.6%), in other places; and 7 (4%) do not work. A study made in order to trace and analyze the CEP profile of the Amazonian University also pointed out that, while there is considerable diversity with respect to the profession of researchers, there is a strong presence of university professors among professionals [12]. Whereas the research bases are in academy training, it can be said that the prevalence of university teachers (54.9%) among researchers is directly related to the need for joint action between teaching and research.

As for the final situation analysis of the protocols after first evaluation performed by reviewers, it was noted that 16 (9.1%) have been disapproved, 22 (12.6%) were approved and 137 (78.3%) were pending. A research carried out in order to report the experience of the CEP of the State Department of Health (SES, , acronym in Portuguese) of the Federal District (DF), Brazil, for 10 years from its foundation, found that the low percentage of non-approved protocols can be understood as a reflection of educational activities promoted by the committee [13]. Another study conducted at the School of Nursing (EE, acronym in Portuguese) from the University of São Paulo (USP) also pointed out that, of the 399 projects examined, 232 (58.2%) were approved with pendency and only 5 (1.3%) have been reproved [14].

Figure 1. Reasons for pending present in research protocols reviewed by a CEP of the city of Divinópolis/MG, Brazil (n = 175).

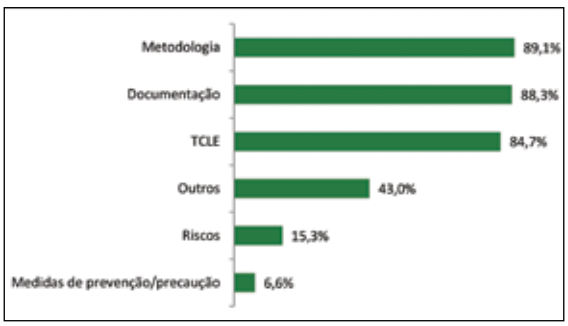


Figure 1 shows that the majority of protocols (89.1%) consisted of disputes relating to the methodology. It is important to note that in the "Other" item were included those protocols that had disputes related to incomplete information, errors in the budget, inclusion and exclusion criteria, covering 43% of the protocols. It should be noted that in all pending protocols there was two or more explanatory pending.

Research carried out by other authors [12] also indicated many of the pending issues identified in the research included in this study protocols, since more often found in the pending protocols evaluated by the CEP collegiate refer to the revaluation of IC request (30%); incomplete information on the cover sheet (25%); lack of information on the type of study

in methodology: sampling, inclusion and exclusion criteria, form of allocation and analysis (20%); missing or incomplete budget sheet (12%); *curriculum vitae* of all cited researchers: incomplete or missing (9%); other factors (4%).

Description of the risks in research protocols

Regarding the description of risks in the protocol, from the 175 researchers, 88 (57.1%) rated their projects as risk-free and 66 (42.9%) rated as minimal risk, among these 28 (42.4%), although they rated their projects as having minimum degree of risk, claimed the ethical aspects that research does not offer risks to the subjects, since it was only a questionnaire / interview. This difference allows the assumption that among researchers there is a tendency to minimize the possible risks of the studies.

As for the other 38 projects containing description of the risks in the ethical aspects (57.6%) were identified two venture arrangements in the descriptions: Psychological, intellectual and/or emotional risks, as well as risks of physical and organic order. Among the first were found: the possibility of embarrassment to answer the questionnaire; discomfort; stress; breach of confidentiality; damage; tired to answer questions; and anonymity break. The second type, the following risks have been specified: bleeding, pain and even life-threatening. It must be said that among the research protocols analyzed, 21 (12%) did not contain the referral form, which made it impossible to evaluate the researchers classified and described the risks of their research.

It is noticed that, among researchers, it is common to classify the risks of research as being non-existent. Contributes to this perception, a study conducted in order to understand the risks in the use of questionnaires / interviews, according to which 18 researchers also said there is no type of risk in their research with questionnaires or interviews. However, the authors emphasized that such instruments can be considered as possible causes of damage, discomfort and embarrassment when there is lack of care in preparing the content and mode of application. They also noted that, depending on the type of question, the questionnaire may cause unusual levels of embarrassment, causing negative experiences [15].

Description of precautionary measures / prevention in research protocols

About pointing precautionary measures/prevention documented by the researcher in their research projects, it was observed that 65 (37.1%) did not mention such measures, while 110 (62.9%) identified the the following ways: responses will be confidential; the questionnaire are not identified by name so that anonymity is maintained; individuals receive prior clarification about the research; the interview can be stopped at any time; reading of IC, legal authorization when subject is vulnerable, psychological assistance if necessary; privacy to answer the questionnaire; guarantee of confidentiality; voluntary participation and consideration of vulnerability, if any.

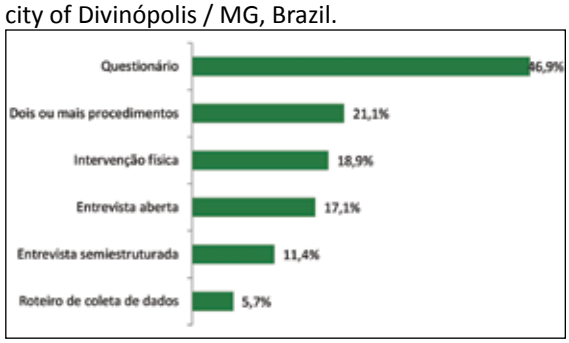
Therefore, among researchers, although only 38 (20.1%) have described the risks of their research in the protocols, 110 (62.9%) recorded the precautionary measures/prevention. It was also noted that researchers can identify the general safety/prevention, but have some difficulty in pointing out the risks. You can see in the analysis of protocols, the strong association between risk and physical, evidenced by the fact that most of the descriptions identifies losses of organic nature. However, to limit risk to this dimension is reductionism, is the same as not perceiving humans as a social individual, with values, culture, beliefs and emotions. The impact arising from the use of non-invasive research tools in the physical body, such as questionnaires or interviews, is often not considered; soon, the damage is not fully exploited [15].

Although not made *in* humans but *with* humans, qualitative research can cause damage or bring harm to those who participate in the study, and this possibility needs to be assessed with the same care that is used in the tests that affect the organic dimension. Furthermore, with the research *with* human beings, there are the ethical dilemmas involved in qualitative research in health go, since this is based on the methods of the humanities, and not in biomedical experimental methods. However, it is necessary to complement that, much more than the existing methodological differences between the human sciences and biomedicine, are present also the epistemological differences [16].

In the face of such differences and peculiarities, points up the need for specific regulations for the humanities to address the ethical dilemmas involved in epistemological research, which are alien to the biomedical research model observed since Resolution 196/96. Therefore, we emphasize the importance of raising issues towards the improvement of the analysis of the ethical implications of anthropological research and the development of proposals on the regulation of ethical procedures considering the landmarks of ethnography [16].

Still on the above, it is added that this regulation should not be restricted to research activity in academia or research institutions, but should be comprehensive, including aspects of activities of non-governmental organizations (NGOs) and government agencies that promote social policies. After all, even if NGOs conduct anthropological research and make use of the same tools and techniques of research, its activities are rarely supervised by the bodies responsible for ensuring compliance with regulation [17].

Figure 2. Instruments and/or data collection procedures used in research submitted to CEP of the city of Divinópolis / MG, Brazil.



As indicated in Figure 2, most of the research (46.9%) were performed by means of questionnaires. It is common to use interview and questionnaire in the research field, and the questionnaire was the most used instrument for collecting information. It dos not need not be restricted to a certain number of issues, but it is advised that it is not too long to avoid discouragement of the researched [15]. It must be said that among the researchers, 27 (21.1%) chose to collect data using two or more types of procedure, for which the sum of the percentages in Figure 2 exceeds 100%.

Risks of IC

Regarding risk category of section IC, it was noted that, of the 175 researchers, 117 (66.8%) did not describe the risks in IC and 36 (20.5%) did. It is inferred that the fact that most have not described the risks in the IC may be associated with word classification "risk" by the researchers, considering that it can "scare" the participants to be very "strong", as often is associated with physical risks and the relationship between life and death. This consideration becomes even more relevant the requirement of description of the risks in all research projects, in the text and also in the IC, which must be attached to the research protocol for review by the CEP/Conep [18]. Also identified in the protocols IC's waiver request in 17 of the analyzed projects (9.7%), because for being a documentary research. Furthermore, it was observed that 5 protocols (2.9%) did not have their IC, for unknown reasons.

Description of precautions/risk prevention in IC

Finally, on the requirement of description of the measures of prevention/precaution in IC, it was observed that, of all researchers, 10 (6.5%) did not describe it and 143 (93.5%) described them directed to the guarantee of confidentiality and secrecy, the withdrawal of participation of the research at any time and psychological assistance guarantee, if necessary. It is worthy to remember that 17 researchers asked IC waiver and 5 protocols did not bring the IC attached. The description of the risks and benefits of participation of subjects in research, as well as the measures of prevention and protection aimed at them, is inherent to the research function and own of their role of who participate in the experiments. As a result, it advocates that such a description follow the prescription of the proposed protocol model by CEP.

Final considerations

The development of this study showed that the researchers, although they have identified, for the most part, the safety/prevention measures in the research protocol and in the informed consent, had difficulty in describing the risks involved in their research, both in the protocol and in the informed consent. Note the fact that many of the researchers have not described the risks of their research because it uses questionnaires and/or interviews as a means of data collection. Note that in Resolution 466/12 - providing for the possibility of establishing specific rule to regulate ethics in social science research, which typically use techniques classified as qualitative - a description of the risks is considered mandatory and probably should be maintained in the proposed guidelines for these areas.

In this sense, just as there is a significant difference in methodology between quantitative research and qualitative research, there in the midst of this last important differences in the data collection technique that must be well known and considered by the researchers. In fact, what is called qualitative research involves from the application of data collection instruments, closed or semi-structured, to the interview and participant observation. The difference in the production, description and analysis of information process in each of these forms of data collection is very significant and needs to be known in depth by researchers in order to avoid the

subsumption of the risks to participants by hiding them under broad definitions, considered harmless, as “qualitative research” or “questionnaires”.

Whereas often the researcher makes use of questionnaires and interviews in their research, it is very important for him to know the possible risks involved in such procedures, in order to adopt measures of prevention and protection. It is noteworthy, therefore, the importance of promoting training of interdisciplinary nature for researchers, so that they are informed about all areas of the Brazilian ethics legislation regarding researches involving human subjects, as well as the specifics of the techniques of quantitative research and qualitative, both in the biological sciences and in the behavioral sciences - those related to psychology and psychiatry - and the sciences from social areas.

Besides providing a favorable moment for the joint ethical reflection, interdisciplinary training can speed up the process of evaluating the research project, as researchers, properly understood, will have less difficulty in identifying the risks and associate them with the precautionary measure/prevention and hence the approval of their projects will be faster. The most important of this process, however, is that this knowledge will bring more security to the participants of the research, as they will be informed about the processes and procedures unequivocally.

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