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Moral and/or ethical issues in research ethics committees

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Abstract

The objective of the study is to analyze moral and/or ethical issues experienced by members of research ethics committees when performing their activities and the strategies used to deal with those issues. This is a qualitative study with 39 individuals that participated in committees in Salvador, Bahia, Brazil. Data were collected in October 2020 using a self-administered online questionnaire developed using Google Forms. Results showed that participants underwent conflicts of interests and values, and also faced dilemmas, and the strategies used to deal with those issues were exchanging of experiences and sharing of ideas and opinions. It is concluded that members of such committees experience moral and/or ethical issues and seek to deal with them via strategies that favor the development of research according to appropriate ethical and methodological criteria.

Keywords: Committee membership. Ethics committees, research. Ethics, research. Conflict of interest. Conflict, psychological. Prisoner dilemma.

Resumo

Problemas morais e/ou éticos em comitês de ética em pesquisa

O objetivo do estudo é analisar problemas morais e/ou éticos vivenciados por membros de comitês de ética em pesquisa durante suas atividades e as estratégias utilizadas para solucionar esses problemas. Trata-se de pesquisa de abordagem qualitativa, com participação de 39 membros que atuavam em comitês em Salvador/BA, Brasil. Os dados foram coletados em outubro de 2020 por questionário on-line autoaplicado na plataforma Google Forms. Os resultados evidenciaram: vivências de conflitos de interesses e de valores, bem como dilemas; e utilização de trocas de experiências e compartilhamento de ideias e opiniões como estratégias para solucionar esses problemas. Conclui-se que os membros desses comitês vivenciam problemas morais e/ou éticos e buscam solucioná-los por meio de estratégias que favorecem o desenvolvimento de pesquisas conforme critérios éticos e metodológicos adequados.

Palavras-chave: Membro de comitê. Comitês de ética em pesquisa. Ética em pesquisa. Conflito de interesses. Conflito psicológico. Dilema do prisioneiro.

Resumen

Problemas morales y/o éticos en los comités de ética de investigación

El objetivo del estudio es analizar los problemas morales o éticos experimentados por los miembros de los comités de ética de investigación durante sus actividades y las estrategias que utilizan para resolver dichos problemas. Se trata de una investigación de enfoque cualitativo, con la participación de 39 miembros que actuaban en comités en Salvador, Bahía, Brasil. Los datos se recopilaron en octubre del 2020 por medio de un cuestionario en línea autoadministrado en la plataforma Google Forms. Los resultados mostraron experiencias de conflictos de intereses y valores, así como dilemas; y el intercambio de experiencias, ideas y opiniones como estrategias para solucionar dichos problemas. Se concluye que los miembros de estos comités experimentan problemas morales o éticos y tratan de solucionarlos mediante estrategias que favorezcan el desarrollo de investigaciones de acuerdo con criterios éticos y metodológicos adecuados.

Palabras-clave: Miembro de comité. Comités de ética en investigación. Ética en investigación. Conflicto de intereses. Conflicto psicológico. Dilema del prisionero.

Research

The authors declare no conflict of interest.

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Even though the *Nüremberg Code* emphasizes medical ethics, reconciling Hippocratic ethics and the protection to human rights, the *Code* was a landmark for research participants' interests and their autonomous decision making to be respected [1,2]. Influenced by this document, other guidelines were also created to ensure research participants' well-being, such as the *Declaration of Helsinki* [3,4]. Thus, the first revision of this declaration, in 1975, established the mandatory submission of a research project involving human beings to prior analysis by an independent research ethics committee (REC – in Portuguese, *comitê de ética em pesquisa* – CEP) [5].

In Brazil, RECs and the National Research Ethics Commission (Conep), which together compose the CEP/Conep System, are responsible for the social control of research involving human beings. Thus, according to Amorim [6], the protocols of these pieces of research are revised for confirmation of whether they are in accordance with previously defined ethical and moral precepts and adequate scientific foundations.

This control is necessary to protect research participants, as it cannot be assumed that regulations alone guide the researchers' conduct. At the same time, Barbosa, Corrales and Silbermann [7] consider that being responsible for this control is challenging due to the evolution of scientific knowledge and the diversity of means to plan and develop research.

Despite the guiding precepts, some research in Brazil remains being carried out without complying with ethical principles and scientific foundations [8-10]. Furthermore, scientific progress, as an inherent part of human potential, imposes new situations to be discussed; then, the precepts should be renewed. From this perspective, in the performance of their activities, it is possible that members of the CEP/Conep System face moral and/or ethical issues arising, for example, from the violation of legal determinations by REC members, institutions and/or researchers, or even situations related to scientific misconduct.

Indeed, moral issues require solutions in the concrete case. Thus, according to Vázquez [11], when making their choices, someone reflects on the best conduct to take regarding a certain action, and this "investigation" becomes the object of their reflections and practical morality gives way to reflexive morality, which demonstrates the fine line between morals and ethics. From this perspective, if morality "observes" the action and the immediate reflection that can be made about it–deliberation in the face of moral dilemmas–, ethics lends itself to elucidating the concepts necessary for moral reflection–the foundation of moral norms; definition of criteria endowed with moral value; investigation into the conditions of imputable action, among other things.

As with the moral question, several alternatives to deal with ethical issue may exist, so that it can present itself as moral uncertainty, moral suffering, and dilemmas. Moral uncertainty occurs when someone goes through a situation one deems inappropriate or incorrect and feels tension, frustration, or even discomfort, but they are not sure or aware that the situation experienced is part of an ethical issue. In turn, moral suffering arises when, in a given circumstance, the person knows the correct attitude to take but feels prevented from following their conscience for some reason [12].

Dilemmas occur when it is necessary to choose one alternative over another [13]. In situations where someone must pick between options that contradict their principles and/or values, this person experiences both a dilemma and a conflict [14]. When it comes to social relationships, conflicts are manifested by antagonism regarding ideas, interests, opinions, and values [15].

In view of these considerations, the research question arises: what are the moral and/or ethical issues experienced by REC members during their activities and what are the strategies used to deal with them? The objective of the study is to analyze the moral and/or ethical issues experienced by REC members during their activities and the strategies used to deal with those issues.

Method

This is a qualitative study with data collected through a questionnaire consisting of 40 open and closed-ended questions–some with the possibility of marking more than one alternative – developed by the researchers. The questionnaire was developed using Google Forms and took respondents about 15 to 20 minutes to complete.

The study was developed at RECs located in Salvador, Bahia, Brazil, with data collection from September 10 to October 13, 2020. Ten RECs were selected, distributed as follows: one REC established in a state higher education institution (HEI); seven RECs established in HEIs linked to a federal public body; two RECs established in public hospitals linked to a federal public body. To select the RECs participating in the study, the fact that they analyze research protocols from various areas of knowledge and review protocols mainly from the health sciences was taken into account.

After receiving the REC's approval opinion, each institution and their respective REC were sent a notice of research approval with a copy of the detailed opinion. RECs were also sent a request for providing their members' contact information. The initial contact then took place by messages via email and/or the WhatsApp application.

Inclusion criteria were defined as: being an effective REC member and responsible for analyzing and/or issuing an opinion on research projects. Exclusion criteria were defined as: being on leave, on vacation, or away for any reason. After analysis, it was possible to select 39 individuals to participate in the study.

In the development of this study, the ethical aspects established in Resolution 466/2012 of the Brazilian National Health Council (CNS) [16] were respected. Likewise, the bioethical principles of autonomy, beneficence, nonmaleficence, justice and equity were followed, as well as the principles and values adopted by the 1988 Federal Constitution of Brazil [17], with an emphasis on respect for the human being's dignity and people's self-determination.

As a result, the vulnerability of people who, for health and/or personal reasons, could not contribute to the study was recognized. Also, to ensure the confidentiality of the information and the anonymity of participants and research sites, the letters "MC" followed by numbers – "MC 1," "MC 2" and so on – were used to refer to the REC members.

Participants were informed about the research aspects–objectives, methodology, possible risks, benefits, confidentiality and anonymity, freedom not to participate, among others–and that they could withdraw from the study at any stage without any penalty. The participant signed a virtual informed consent form when they agreed to move on to the questionnaire stage.

In this sense, answering the online questionnaire, reading the informed consent form, and agreeing with the research were considered *sine qua non* conditions–described in Google Forms as "mandatory." A copy of the participant's informed consent form was made available as a PDF file by means of a link included in the questionnaire.

Data were separated per zip code and organized into tables in Microsoft Word 2010. Then, a full reading of this compilation was made, comparing it with form information, to check if the transferred data were in accordance with the participants' answers. To examine the answers, content analysis developed by Vietta [18] was used, called "triad configuration (humanist-existential-personal)."

This method was originally developed and used in qualitative research in the field of psychiatric nursing and mental health. Its theoretical-philosophical references are humanism, existentialism and personalism, considered adequate by the author to explain that each person is a unique, singular being.

For this study, the references adopted were: ethical norms of research involving human beings; theoretical-philosophical references of ethics and bioethics; literature on the subject, and principles adopted by the 1988 Federal Constitution. This technique enabled the essence of the descriptions made by each participant on the online questionnaire to be captured and analyzed them with regard to their singularity, without making generalizations.

Results

The research group was composed of 39 participants; 16 women and 23 men, and most were married or living in a stable relationship (23), brown (20) and Catholic (18). Four of them were coordinators, five vice-coordinators, and five were user representatives. As for education, all reported higher education, most with a master's degree (21).

From the careful and exhaustive reading of the participants' answers, interpreted according to triangulation of the references adopted, thematic categories emerged from units of meaning.

Such units were used to understand the moral and/or ethical issues faced by REC members during their activities and the strategies used to deal with those issues.

Moral and/or ethical issues experienced

In their descriptions, the participants stated that they face conflict of interests and values and also dilemmas in their activities at the REC. Conflict of interest occurs when they receive research protocols for evaluation coming from known people, and because of conduct of researchers who use the personal relationship to expedite the resolution of pending issues of their projects, according to MC 25 and MC 37. In this context, MC 13 reported declining to be a rapporteur on the project when he recognized a conflict of interest.

"Evaluate projects of graduate colleagues with whom I have frequent personal contact" (MC 25).

"Researchers (...), because they know the REC members, use the personal relationship to expedite their process' pending issues, which should be done by Plataforma Brasil" (MC 37).

"Projects with conflicts of interest (...) in these cases we refuse to be a rapporteur and pass it on to another colleague" (MC 13).

MC 6 and MC 30 reported conflict of interest in a research project with a budget for researcher per participant, and in the REC members' working relationships, respectively.

"I analyzed a project with expected funding in clinical trial (...) with a budget (...) for the researcher per participant" (MC 6).

"In a few moments, I observed some members trying to be more flexible in the final decision on research protocols. This fact may be related to the working relationships between professors and also professionally, considering that some members are part of the educational institution faculty and close to research professors" (MC 30).

In turn, conflicts of values faced by REC members occur, according to MC 30, when discussions about protocols take place and/or, according to MC 10, in case of disagreement with the methodologies used in the research protocols considered. In certain circumstances, the REC member states positions are accepted by rapporteurs even being divergent from what they defend. In this case, MC 20 accepts a decision that may be contrary to their beliefs, values and academic knowledge, configuring a conflict of values.

"What I experience the most are situations of divergence of opinions/ideas expressed during discussions about research protocols" (MC 30).

"Disagreeing with methodologies employed by colleagues in their research" (MC 10).

"On several occasions, I am a defeated vote and I need to accept it even being the rapporteur" (MC 20).

Regarding the dilemmas, REC members claimed to face them as a result of the choices made when analyzing research projects. Thus, sometimes a dilemma occurs as a result of suggestions and/or recommendations made to the researcher, sometimes during the discussion about no need of filling the informed consent, as stated by MC 21 and MC 37:

"My postures sometimes impact on suggestions or recommendations to the researcher. I'm not sure if I'm against science in some ways" (MC 21).

"At the time, REC members tended to authorize the exemption [from the consent form] *but, given the ethical dilemma, isolated decision-making was not comfortable"* (MC 37).

Strategies: solution for the issues experienced

Participants consider different strategies to deal with the moral and/or ethical issues experienced, such as exchanging experiences, sharing ideas/opinions, and pedagogical practices. According to the statements of MC 34, MC 20 and MC 30, exchanges, used to settle moral and/or ethical issues, occur through life experience, practical situations, and active listening:

"In our life experience" (MC 34).

"In practical situations" (MC 20).

"Listening to colleagues, listening carefully to the opinion of each member, coordinator and

vice-coordinator, considering the regulations of the institution and the REC itself" (MC 30).

Discussion and sharing of ideas with the committee members and pedagogical practice are other strategies considered by REC members to deal with moral and/or ethical issues, according to statements:

"I discuss with another REC member to settle issues together" (MC 2, MC 23, MC 26).

"In the collective judgment through discussions in meetings with other REC colleagues" (MC 25).

"When there are doubts about which procedure to follow, after discussions and arguments, I analyze arguments for and against and the individual decision is based on this attempt at ethical balance, so that barriers to conducting research are not created, nor risks for individuals [who are] *research subjects"* (MC 37).

"Constant sharing of issues at biweekly collective body meetings, when necessary, and frequent sharing of doubts and questions among colleagues. All conflicts and doubts are decided by a collective body, which makes us comfortable because no single member is responsible for any decision" (MC 13).

"Provide, pedagogically, the necessary clarifications" (MC 17).

Consultation with another REC was cited by MC 37 as a strategy used to deal with moral and/or ethical issues. Thus, it was stated that there is more confidence in the case of document exemption–for example, consent forms in research involving minors–when a similar situation has already been discussed in another REC and the solution is guided by a judicial decision.

"Discussion about no need of the consent form that would be signed by parents/guardians of minors (...) at the time we consulted another REC that received the regional project, and it had obtained an judicial authorization for not using the consent form (...) isolated decision-making was not comfortable and given the prerogative, this was accepted in our REC" (MC 37).

Discussion

The descriptions of moral and/or ethical issues dealt with by REC members allowed us to understand that, within their respective committees, there are conflicts of interest related to different situations. The participants reported cases in which they analyze pending issues solved by researchers and/or make more flexible decisions about research protocols of known people, and identify a research protocol in which the researcher has a budget per participant.

Conflicts of interest favor the partiality of a REC member's professional judgment, as the appreciation of a research project by close or known people can compromise the quality of the analysis. Similarly, evaluation of a research project involving a REC coordinator appointed by the heads of the institution can also compromise a REC member's independent performance [5]. In this context, it is necessary to request the removal of the member who has the protocol under evaluation during the presentation and discussion of the rapporteur's opinion and preparation of the substantiated opinion.

CNS Operational Standard 1/2013 [19] highlights, among other situations, that the conflict of interests within the scope of the RECs can arise from working relationships; conducting consultancy; existence of a partnership and/or ownership of shares in a research funding institution, and exercise of power in the institution that maintains the REC. Therefore, at the time of application or acceptance of nomination to be a REC member, the candidates must declare in writing that they have autonomy and independence to perform the function [19]. Accordingly, this study shows that, when the existence of a conflict of interest is perceived, the strategy employed is to pass on the function of rapporteur to another member.

As most of the participants in this study claimed to work at the institution where their collective body was established, it is inferred that the occurrence of conflicts of interest related to the analysis of projects of people known to REC members is not uncommon. However, despite these situations, REC members act to protect the research participants' interests and rights, and this should be seen by them as a primary duty.

Furthermore, REC members render a public interest service and therefore should have autonomy and independence in the exercise of their function, in the sense of not allowing private interests to supplant the public interest. For this reason, the members should guide their conduct, among other guidelines, by the principles of impersonality, as stipulated in the 1988 Federal Constitution [17].

In a funded research protocol in which the researcher receives a budget per participant, this researcher's professional judgment may be unduly influenced, leading them to privilege a secondary interest to the detriment of a primary duty [20]. This is because, as explained by Paiva and collaborators [21], when there is economic interest, research, which should be oriented towards the collective good, has its investigation conditioned.

In this case, conflict of interests can be seen from different perspectives: that of the researcher, that of the research participants, that of the funder, and that of society itself. The primary duty of every researcher is to carry out research involving human beings in accordance with ethical and scientific foundations and they should not be affected by other interests.

The case of researcher-related conflict described by a REC member in this study raises the following consideration:

There is potential conflict of interest in situations in which the coexistence between the interest that the researcher should have in advancing science and interests of another nature, even if legitimate, can be reasonably perceived, by the researcher or by others, as conflicting and harmful to the objectivity and impartiality of scientific decisions, even regardless of the researcher's knowledge and will (...). *In these situations, the researcher should consider, depending on the nature and severity of the conflict, their aptitude to make these decisions and, eventually, they should refrain from making them* (...). *In cases where the researcher is convinced that a potential conflict of interest will not impair the objectivity and impartiality of their scientific decisions, the existence of the conflict should be clearly and expressly declared to all parties interested in these decisions, as soon as they are taken* [22].

The situation of conflict of interest in a clinical trial research protocol reported by MC 6 was understood as potentially capable of impairing the objectivity and impartiality of the researcher's scientific decisions due to the coexistence of primary and secondary interests. These interests are highlighted in clinical trials, because, according to Silva, Ventura and Castro [23], they can contribute to the economy of countries involved with job and income generation and technical-scientific development, in addition to bringing direct benefits to research participants and the local community, among others.

However, from the perspective of Alves and Tubino [24], clinical research involves some type of intervention, and most of the time the participants have little understanding of the risks involved and/or do not know the procedures for going to court when they are harmed. For this reason, in research practice, it is recommended that conflicts be described objectively. Moreover, all research involving human beings, without exception, must have their protocols analyzed by a REC.

Therefore, regardless of whether the researcher follows the guidelines of the code of good scientific practice, the REC must verify if the measures explained in the research protocol are clear and sufficient to protect and defend the participants' interests. In this sense, detailing of the research project budget is relevant so that it is possible to assess whether the amount to be received by the researcher can induce them to change the risk to benefit ratio for research participants. Likewise, the researcher should be discouraged from basing the budget solely on the number of participants, as guided by the Operational Manual for Research Ethics Committees [25].

Participants in this study also described an experience of conflict of values manifested by differences of ideas or opinions during discussions about protocol. This may be related to the fact that REC members have different worldviews, knowledge, and experiences. These divergences, when exposed with respect and plausible justifications, enrich the discussions and can help in the construction of a research project that meets the ethical and methodological aspects of research involving human beings.

The REC rapporteur, after studying a question or evaluating a research protocol, presents the case to the other members for discussion about ethical and methodological aspects, but the decision that will prevail is that of the collective body [25]. Therefore, all REC members have autonomy and independence in their actions, and disagreements of ideas and opinions among members are part of the process.

The dilemmas experienced by the participants of this study are related to the suggestions or recommendations made to researchers and the discussions about no need for the informed consent form. In these cases, for example, when deciding on protocol pending issues, the REC member suggests that the researcher adjust the research project and/or decide to maintain the informed consent form. This stance leads this REC member to question whether they would be in favor or against scientific development.

The ethical dilemma that arises in these situations transcends the simple act of choosing between two apparently opposing alternatives, as it involves the scope of ethical conflicts. According to Freitas and Fernandes [26], ethical conflicts occur because people have different values, beliefs, experiences and ethical, human, and professional training.

In addition, it is inferred that the ethical dilemma experienced by the REC member in this study may be accompanied by suffering or discomfort, and it is not easy for them to decide which of the alternatives would be the most appropriate to solve the ethical problem experienced. Nora, Zoboli and Vieira [27] corroborate this idea about ethical problems by considering that these have several courses of action and that to solve them one must think of the most appropriate solution for the specific case.

In the case of REC members, balance in decisions is fundamental, as one right does not have to cease in order for another to exist. Thus, the development of a medicine does not justify disrespecting the dignity of research participants or their exposure to dangerous situations, nor the failure to recognize their situation of vulnerability [28]. Therefore, if the participant's rights are as relevant as scientific development, it is necessary to reflect, deliberate and consider before deciding between the alternatives, always having the human being as a reference.

For this reason, when considering a research protocol, the REC member must ensure that the participant's rights are being considered and solve the dilemmas experienced to avoid violation of human rights. Protecting the rights of potential research participants is, according to the World Health Organization, the main responsibility of a REC, and its ultimate goal should be to promote research within high ethical standards [29].

When evaluating projects and settling moral and/or ethical issues, the REC member should consider the research participant as a person with rights that must be respected and protected. In order to settle moral and/or ethical issues, the participants of this study express as strategies the exchange of experiences, sharing of ideas, and pedagogical practices. In this sense, collaborative and cooperative learning are considered methodologies capable of promoting more active learning, as they stimulate critical thinking, interaction between people, negotiation of information, and problem solving [30].

Within the REC, collaborative and cooperative learning have been practiced by exchanging experiences – between members of the same REC or not –, discussions during REC meetings, and sharing of ideas and opinions. The continuous training of the participants of this study also occurs through these exchanges, which enable them to make decisions and settle practical issues faced during the analysis of research protocols involving human beings.

With this, they are prepared for ethical decision-making when issuing technical opinions and, where applicable, their decisions become a reference for other RECs. This training is essential for the work developed by REC members to produce adequate ethical reviews [31], with a positive impact on guaranteeing and protecting research participants.

Using pedagogical practices when settling moral and/or ethical issues demonstrates that the educational function developed by the RECs studied also involves the researchers' training. Guidelines and/or recommendations made by REC members to researchers make it possible to improve the quality of projects so that they can be developed according to ethical aspects of the research [25].

Final considerations

The study revealed that REC members experience moral and/or ethical issued expressed as conflicts and dilemmas, and the strategies used to deal with them are exchanges of experiences, ideas and opinions – among themselves or with members of other RECs – and pedagogical practices. In this context, pedagogical practices are relevant for the development of the educational function of RECs with regard to researchers.

These practices should thus be seen as applications of the principle of efficiency in the REC member's performance because, as researchers are trained, research can be developed within appropriate ethical and methodological criteria. Therefore, the use of pedagogical practices instead of merely pointing out flaws, indicating pending issues and approving or not research protocols, creates a space in the REC for members and researchers to perceive each other as responsible for the construction of scientific knowledge.

The lack of literature and the REC members' low adherence can be mentioned as limitations to this study. Even so, the results enabled the discussion and analysis of the information described by the study participants and can be applied to REC members who experience similar circumstances.

Studying moral and/or ethical issues experienced by REC members in their activities and knowing the strategies they use to deal with these issues can support public policies aimed at research involving human beings. Besides, it can help and stimulate educational practices for REC members, scholars and researchers, enabling responsible action in research conduction.

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Rosinete Souza Barata conceived the study, collected the data and, assisted by Kleverton Bacelar Santana, wrote the text. All authors analyzed and discussed the data and critically reviewed the manuscript.

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