

Awareness of University Professors about the role of the Research Ethics Committee

Gabriela Maria Cavalcanti Costa ¹, Renata de Oliveira Cartaxo ², Mayara Lima Barbosa ³, Suely Deysny de Matos Celino ⁴

Abstract

The aim of this qualitative study was to understand the awareness of professors in a Brazilian Public University about the performance of the Research Ethics Committee in the assessment of protocols as well as their understanding on the meaning of the committee's recommendations. Through a semi-structured interview, it was developed between December 2010 and June 2011 with teachers of different subjects of a State university. The technique of content analysis was applied in which two categories were identified: regulation of research involving humans and Submission of Protocols for the CEP evaluation. Speeches reveal that teachers know the Resolution 196/96 in an unsatisfactory manner. They positively evaluate the performance of the CEP, although they have limitations regarding the knowledge about the procedure of ethics assessment. For professors, the CEP assessment meant a necessary process to ensure rights of research subjects and allow subsequent publication of data.

Key words: Bioethics. Faculty. Ethics committees, research.

Resumo

Conhecimento de docentes universitários sobre a atuação do Comitê de Ética em Pesquisa

O objetivo desse estudo de caráter qualitativo foi compreender o conhecimento de docentes de uma universidade pública brasileira acerca da atuação do Comitê de Ética em Pesquisa (CEP) institucional na apreciação de protocolos, bem como seu entendimento sobre o significado das recomendações do comitê. Foi desenvolvido entre dezembro/2010 e junho/2011 com docentes de diferentes áreas do conhecimento de uma universidade estadual, a partir de entrevista semi-estruturada. Utilizou-se técnica de análise de conteúdo, identificando-se duas categorias: regulamentação de pesquisas envolvendo seres humanos e submissão de protocolos à avaliação do CEP. Os discursos revelam que os docentes conhecem a Resolução 196/96 de forma insatisfatória. Avaliam positivamente a atuação do CEP, ainda que possuam limitações quanto ao conhecimento sobre o procedimento de avaliação ética. A avaliação do CEP significou para os docentes processo necessário para garantir direitos dos sujeitos participantes e permitir posterior publicação dos dados.

Palavras-chave: Bioética. Docentes. Comitês de ética em pesquisa.

Resumen

El conocimiento de los profesores universitarios sobre el papel del Comité de Ética en el protocolo de evaluación

El objetivo de este estudio cualitativo fue comprender el conocimiento de los profesores en una universidad pública brasileña sobre actividades del Comité de Ética en Investigación (CEP) en la evaluación de los protocolos institucionales, así como su comprensión del significado de las recomendaciones del comité. Fue desarrollado entre diciembre de 2010 y junio de /2011 con profesores de diferentes áreas temáticas de una universidad estatal desde la entrevista semiestructurada. Se utilizó la técnica de análisis de contenido identificándose dos categorías: reglamentación de investigación con seres humanos y presentación de protocolos a la evaluación del CEP. Los discursos revelan que los profesores conocen la Resolución 196/96 insatisfactoriamente. Evalúan positivamente el desempeño del CEP a pesar de tener limitaciones en el conocimiento del procedimiento de evaluación ética. La evaluación del CEP significó para los docentes un proceso necesario para garantizar derechos de los sujetos de investigación y permitir la posterior publicación de los datos.

Palabras-clave: Bioética. Docentes. Comitês de ética en investigación.

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1. **Doctor** gabymcc@bol.com.br 2. **Graduate** renacartaxo@gmail.com 3. **Graduate** may.lb@hotmail.com 4. **Masters** deysny@hotmail.com – State University of Paraíba (UEPB), Campina Grande/PB, Brazil.

Mailing address

Suely Deysny de Matos Celino – Rua Jose de Alencar, 991, apt. 202 Prata CEP 58428-750. Campina Grande/PB, Brazil.

They declare that there is no conflict of interests.

According to Araújo ¹, the search for awareness dates back centuries. The need for a deeper understanding of the world led to the creation of structured systems of knowledge organization, and so the scientific knowledge. Universities gradually incorporated this practical sense of awareness, but more and more it is expected of them to create useful knowledge and graduate people capable of meeting the requirements of a working world shaped by the same science and technology.

In Brazil, the production of knowledge through scientific research has been more widely diffused in higher education institutions, constituting the privileged locus of the development of researches that gather useful knowledge to society ². With that, it has also increased the restlessness towards ethics issues revolving the field of research.

The concern to evaluate ethics issues related to the research involving human beings has been consolidated in the review of the Declaration of Helsinki, in 1975, establishing the need for creation of a research protocol to be submitted to consideration, discussion and orientation of an ethics committee. The goal of this initiative was to protect research subjects from possible damage, preserve their rights and ensure ethically correct methods – that is, ensure the respect for identity, integrity and dignity of the human being, as well as social justice ³.

In our country, such requirements were created in late 1980's, when the National Health Council (CNS) approved Resolution 1/88, with health research standards that determined the need for the informed consent and approval of the research protocol by the ethics committee ⁴. Considering the low adherence to the standard, this document was revoked by Resolution 196/96, approving all guidelines and regulatory standards of research involving human beings, incorporating concepts of the principlism in bioethics and maintaining the consent of the individual and the need for previous approval of the study by the ethics committee ⁵.

According to this resolution, committees have a consultative, decision-making and educative nature. All projects involving human beings must be submitted to the Research Ethics Committee (CEP), even when using secondary data ⁶. The CEP is the body acting as the ethical reviser of any research proposal ⁵. The respect for autonomy, non-maleficence, beneficence and justice are the ethic principles that must always be observed in the committee's analysis. The individual consent and the maintenance of privacy of information are also fun-

damental items that must be analyzed before consenting to the development of a research ⁷.

In light of such aspects and aware of the role of the health research to improve the assistance to the population, always respecting the ethics principles that guide such practice, this study sought a reflection on importance of the CEP to meeting the ethical principles in researches. The goal, thus, is to grasp the awareness of professors at a Brazilian public university on the role of the institutional CEP in evaluating protocols, as well as their understanding on the meaning of the committee's recommendations.

Methods

This is a qualitative study carried out between December/2010 and June/2011. It was composed by five graduation courses at Campus I of the State University of Paraiba (UEPB), selected from the courses that showed the higher number of enrolled students, according to the information provided by the Dean of Undergraduate Studies, respecting the maximum for a course through the Science Center. After the deliberation, the following courses were selected: bachelor's degree in Law (Legal Sciences Center), Business Administration (Social and Applied Sciences Center), Physical Education (Biologic and Health Sciences Center), Mathematics (Science and Technology Center) and Literature/Linguistics (Education Center).

To compose the group, we based ourselves on Turato ⁸, who suggests the creation of criteria of inclusion, which at the present study were: being a faculty member at UEPB; having developed a research project in the last semester; being a registered member of a research group at Lattes directory; having previous experience in submitting a project for evaluation at CEP/UEPB; work in the institution for at least one year in the same capacity; and agree to participate freely in the study.

The number of professors selected, at first, was 151. When consulting the Lattes directory, according to the updates, their participation in research groups' directories and guidance in studies in progress or concluded was confirmed; the population was then of 47 professors. However, during field work, 12 faculty members were identified as in leave for capacity building or retired, 6 did not agree to participate in the study and 19 had never submitted research protocols to CEP/UEPB. Thus, 10 faculty members satisfied completely the criteria and agreed to participate in the study.

Semi-structured interviews were used to map the practices and beliefs of specific social universes, as Duarte ⁹ suggests. All interviews were recorded and conducted within the physical space of UEPB between March and May of 2011.

The following questions guided the interviews: which bioethical references rule researches with human beings? Which legal instrument underlies the ethics in researches involving human beings? How to you submit your research for ethics assessment? Which items the research protocol must have? What is a TCLE? Which information related to subjects must be described on the protocol? What are the composition and attributions of a CEP? How do researchers interpret the CEP evaluation?

The most important sentences, ideas and concepts of the reports directly related to knowledge and meaning of CEP's role were sought. This way, the categories were not previously created, but built after successive readings of the material, trying to converge to units of meaning to create themed categories ¹⁰. The first of them was called *regulation of researches involving human beings*; the second *submission of protocols to CEP evaluation*.

To maintain the secrecy and anonymity, the subjects were identified by the first letter of the course, followed by the Arabic algorism corresponding to the order of the interviews, according to Resolution CNS 196/96's recommendation. The study was approved by the State University of Paraíba Research Ethics Committee.

Results and discussion

• *Characterization of subjects*

The faculty members interviewed were 46.7 years old, on average; as for graduation, the mean time was of 22.4 years, with 80% of the faculty members had a doctor's degree and 20% a master's degree. Such reality is similar to the professors' profile in higher education institutions released in the last Higher Education Census, in 2009, characterizing the university professor as 44-years-old and with a doctor's degree ¹¹.

Their role in researches was, mainly, guidance of alumni in term papers (100%) and in scientific initiations (80%), fundamentally cooperating to the graduation of the student body in research, established as a pact with society, aiming to improve life in collectivity ¹².

Theme categories

• *Regulation of researches involving human beings*

In Brazil, the instrument for ethics assessment in research protocols is Resolution CNS 196/96, based on many international regulations: *Nuremberg Code*, *Helsinki Declaration*, *Guidelines for Biomedical Research Involving Human Subjects*, *International Guidelines for Ethical Review of Epidemiological Studies*, among others ⁵.

During the assessment of faculty awareness regarding Resolution CNS 196/96, the instrument was indicated according to the following categories: legal instrument; basic principles of bioethics that guide the scientific community; free and informed consent (TCLE); ethic and scientific requirements necessary; composition and attributes of CEP members.

• *Legal instrument*

When questioned about which instrument ruled researches involving human beings, there was no reference to the name of the regulation, only an approximation on a health area standard, as noted in the following quote: *"It is a technical standard of the Health Ministry about the procedures and the citizens' right to preserve their personal rights"* (PE4).

Other professors' answers varied from TCLE to the instruments for data collection or research protocol. Some even declared not having any knowledge of the instrument ruling the ethics assessment: *"I think they are the survey"* (L2); *"The free and informed consent, I think it's the instrument"* (PE2); *"The research project"* (PE3); *"I don't know which instrument they use for the evaluation, all the ethical issues are left to the Ethics Committee"* (PE2).

A similar discovery was made in the Hardy *et al.* ¹³ research, in which authors state that researchers are not always fully informed on the regulation or even on the existence of the resolution. A concerning fact, considering that if the document and its guidelines are not known by the relevant people, its full use and implementation are compromised.

• *Basic principles of bioethics that guide the scientific community*

The National Policy of Science, Technology and Innovation in Health establishes the respect for the life and dignity of the person as a basic foundation, paying full attention to the ethics issues in health researches. The implementation of high ethic standards in research must be in accordance to Resolution 196/96 and complementary standards ¹⁴.

In order to observe all principles mentioned in the resolution – autonomy, non-maleficence, beneficence and justice – it is necessary for the researcher to follow the ethics demands at research protocols. The speeches of professors below represent the observance of such principles: “I believe it is the respect for life” (LL2); “I believe that you need to present such instruments to the person you are interviewing and make them aware that it won’t harm them” (L2); “It is the secrecy of information, the researcher’s responsibility to keep the data safe [...] I would translate it into the issues of human dignity, respect and social responsibility” (PE1).

Scientists’ goal is to discover new knowledge through the development of relevant research, in an honest and self-interest free manner, acting cautiously on possible dangers and benefits to subjects and communities, ensuring that the risks will be avoided¹⁵. During the conduction of the study there need to be actions aiming at the welfare and granting benefits to the research subjects. For that, the importance of a rigorous risks and benefits assessment must be emphasized – not only individual and immediate risks, but also collective and focused on future problems⁷.

- **Free and informed consent (TCLE)**

In its item IV, Resolution CNS 196/96 states that the TCLE must contain the justification and goals of the research, risks and benefits, chosen methods and other alternatives, contact for assistance and follow-up on research subjects, guarantee of secrecy, necessary previous clarifications and freedom for the subjects to refuse participation, as well as withdraw from it at any time and the means of indemnification and compensation when there is damage⁵.

The following sections of the speeches show the professors’ knowledge on the creation of TCLE: “that I can recall, goals, social relevancy of research, expected social impact, secrecy” (PE1); “Clarity of goals, research’s theme, instruments being used, what will be accessed from the place of research, contact information, the availability of such contact, respect for the under-aged, respect for those who can’t write” (PE4).

Most professors mentioned correctly the requirements evaluated by the CEP related to the TCLE. However, none of the interviewee described completely the parts that must integrate the term. Castilho and Kalil⁷ state in their study that approximately 25% of the rejection of research protocols in the first evaluation is due to flaws in the TCLE. Our

research also shows a deficiency in researchers as to the correct creation of the term. The following speech denotes this type of flaw: “This free and informed consent is usually the standard model provided by the institution that we simply adapt to each research specifically” (L3).

We also observed the existence of researchers who don’t follow the ethics requirements that standardize researches with human beings. The study by Hardy *et al.*¹⁶ confirms such findings, indicating that 62% of researchers didn’t develop their TCLEs, adapting or translating the document – note that 100% of such documents didn’t meet all items on Resolution CNS 196/96.

This reality is extremely concerning, considering that the research involving human beings has as its central ethics issue the development of conditions that allow research subjects to consent basing themselves in an independent and autonomous decision, grounded on reliable information regarding the present and future implications of their participation, which will assure a free choice of consent¹⁷.

- **Ethical and scientific requirements**

Part of the professors proved to be familiar with CEP’s procedure of the evaluation process for research protocols, from submission to issuance of a consolidated opinion. In short, they discuss the process, but no interviewee mentioned a deep awareness on the scientific methodological evaluation, as it is observed in the speech: “We prepare the project, register it on Sisnep, and after it is registered we print the document, sign it and after date and signature, the student takes it to the CEP. And we wait for the assessment” (PE2).

However, some of the interviewees, specially from the legal and human studies areas, seem to be unfamiliar with the recommendations of the Operational Manual for Research Ethics Committee¹⁸, which foresees that the process for ethics assessment of the study be started by registering the protocol in the National Committee for Research Ethics (Conep) and defines that, later, the project be submitted to the responsible CEP, with an attached letter of presentation, identification and consent of the researchers proving knowledge of the content of the project, TCLE and description of its presentation to the interviewee, complete budget of the project and Curriculum Lattes of the main researcher¹⁸. “I don’t know. I submit the project to post-graduation and they evaluate if it needs to be submitted to the committee” (BA1). This unfamiliarity may be related

to the area of each professor, given their little experience with research involving human beings.

Trying to develop a research meeting the ethics principles without knowing where the ethics assessment is based on is also a disturbing fact. In such cases, the professors do not know the ethics and scientific assessment process to which their own projects are submitted. Lima *et al.*¹⁹ point out the feared situation caused by the probability of the existence of a dualistic relation between the scientific and ethics production. Even if the CEPs take on themselves the responsibility of the ethics assessment, approving or not the protocols, it is important that the researcher takes on the responsibility to protect the dignity of the research subject and not only the publishing of his work.

- **Composition and attributes of CEP members**

The following transcripts make reference to the composition of the CEP, according to the interpretation of the interviewed subjects: *“They are researchers from their fields, from different areas”* (BA1); *“Representatives of research entities, such as the university, civilians, research professors, entities representatives”* (PE3).

Even if the professors generally indicated the multidisciplinary and intersection character of the CEPs, it was noticeable that they did it from the institution’s committee formation, manifesting only partial knowledge of this aspect, as well as of Resolution CNS 196/96. This resolution’s item VII specifies that CEPs must be formed by professionals of exact, social and human sciences and by a member of society, representing the institution’s users, as to present a multidisciplinary character⁵.

The following speeches relate CEP attributions according to the majority of faculty-researchers interviewed: *“One of them is exactly the analysis of projects involving human beings from the ethical point of view”* (L1); *“What I understand as an ethics committee is to observe the treatment given to the research subject, how the research treats them, what will be published, what will be needed from the generated data”* (LL1). The ethics assessment of a project involving human beings is the CEPs responsibility, which must evaluate the quality of the research protocol, the risks versus the benefits that the development of the research and its results will evidence and the report of necessary information to the subjects so that the ethical conduct is maintained²⁰.

Another CEP attribution is its consultative and educational character, founding the reflection re-

garding ethics in science⁵, an ability of great importance due to being a formative activity, which sensitizes and instrumentalizes the academic community regarding the principles and standards of ethics behavior for researchers. Such activity can improve future researches, avoiding mistakes that can cause damage to those submitted to the experiments. This function was mentioned only by one professor: *“Coordinate, guide the institution regarding the procedures necessary to authorize researches, to register researches in this bigger system”* (PE1). Thus, it is understood that the professors don’t really recognize the importance of this attribution, presenting a limited awareness of project analysis - which was previously mentioned.

There are other CEP attributions that were not mentioned in interviews, such as receiving complaints of abuses committed by researchers or events that alter the course of the study, being CEP’s responsibility to decide if the study will be discontinued, altered or suspended. When an irregularity is proven, the local CEP must communicate it to Conep/MS⁵.

Additionally, there were a few professors-researchers who revealed not knowing the committees’ attributions: *“No, because I don’t know”* (L3). Others mentioned it incorrectly: *“I think it is being unbiased, avoid being biased, avoid nepotism, unfortunately a lot of professors are neglected”* (LL2). It is important to point out that CEP members must not have a conflict of interest, not as their function, but as a conditioning factor of their role. CEP’s attributions are mentioned in the resolution, and also the items that characterize the creation of a research protocol that respects the principalism references.

Thus, it is understood that researchers are also unfamiliar with Resolution CSN 196/96 itself and, in some cases, reference it in their works only to fulfill CEP’s requirements, or even the magazines’ they intend to publish in, which leads to creation of protocols without due ethical precautions.

Despite that, in general, the advances in research ethics standards cannot be denied. Such progress has led us all to reflect on the issue, making it more current and relevant. But with the increase in representativeness and importance of the researcher’s activities, the number of scientist has grown significantly and, despite the increasing concern with research ethics, it is necessary to know and follow the standards that regulate it, as well as stimulate discussions in all research institutions¹. The analyzed aspects in this topic, the composition and attributions of CEP members, demonstrate the

need to improve knowledge on their role and function.

Submission of protocols to CEP evaluation

In this category we will evaluate the meanings surrounding the understanding of professors regarding the submission of research protocols to the CEP. The category includes the following subcategories: evaluation of CEP's role; evaluation of CEP assessment process; not favorable consolidated opinion; conducted researches; observation of plagiarism in academic research - described below.

- **Evaluation of CEP's role**

CEP's role is centered in assessment and in follow up of the ethical aspects involved in researches. In this sense, CEP aims to cooperate with the development of science, playing its consultative and educational role with the researchers, with the mission to grant protection to the research subjects.

In the speeches of the interviewee, CEP's role regarding the protection of research subjects, as well as their importance for science, became clear: *"It has a fundamental role, which is grant respect to the researched citizen"* (PE4); *"I believe it is a very important place regarding the issue of the contribution to research and science"* (LL1).

However, it was possible to see a misunderstanding of how the CEP analyzes a protocol to verify if the ethical principles are being granted. Resolution 196/96 defines that the scientific records and data that support the research⁵ be attached to the protocols, but the interviewee did not consider it to be CEP's role to analyze the foundation of the research proposal:

"Look, I was once more resistant (...) I thought that the projects were evaluated for items that were not CEP's responsibility, theoretical foundation notes, things of that nature" (PE3);

"But the theoretical issue, maybe the methodological issue, it is for another committee to assess, the committee that evaluates Pibic's projects." (LL1).

The opinion maker must give and appropriate scientific, regulatory and ethical review of the protocol. During the scientific review, the drawing, hypothesis and methods are analyzed. In legal and regulatory review, the practicability of the proposal must be evaluated. At last, the ethical review must

be focused on the subjects, the consent, the bio-ethical principles and conflicts of interests²¹. That way the CEP must not act in a notary and bureaucratic way, applying rigorously the dispositions of the resolution, for this process requires reflection and criticism for the decision-making on the study, including evaluating the ethical parameters implied in its designing and foundation²².

It was also noticed a deficiency as to the implantation of the CEP's educational role to researchers-professors: *"I think the CEP could publicize better its actions so the we could work together"* (L2); *"(..) this greater publicity I mentioned is regarding the ethical issues, but it's still an issue that the committee has overlooked, publicizing it in all centers"* (L1).

CNS establishes that the CEP must *assure the continuous formation of researchers in the institution and promote a discussion on the ethical aspects of researches involving human beings in the community*. The appreciation must reflect along with the researcher about the best way to assure the autonomy of research subjects, searching better resources to inform them, promoting activities such as seminars, lectures, courses and studies about research ethics¹⁸. Freitas²³, in his study about knowledge and leadership practices at CEPs, noticed that some of them presented themselves as groups available to help researchers, trying to demystify CEP's stigma as a bureaucratic and supervisor organ. The accounts of our interviewee evidenced the need for more information on CEP's role and on what is required.

- **Evaluation of CEP assessment process**

Even if the CEP's role was considered important for scientific contribution by the interviewed faculty, although with reservations on its real role, the sentiment revolving submitting a research protocol for assessment varied: *"I'm anxious, because even though we have experience, even if we know that the project has what the committee requires, sometimes it is not clear to them"* (LL1); *"I'm relaxed, I have no rejection towards it. It is necessary to have a committee to assess and judge the scientific research"* (BA1).

The submission of the research protocol to an ethics assessment was understood as a normal step of the research process. Even so anxiety was reported on the eve on the assessment. This feeling was reported as being independent of the researcher's experience and presents itself mainly for fear of not having been clear, of not having been

able to express the proposal in an accessible way to someone who is not in the same study area. Such anxiety also generates an expectation of how much time the researcher will have to execute the proposal: *"I'm anxious until I get the answer, until I know the result of the assessment I get worried, nervous, waiting to be approved, hoping nothing is rectified so I have enough time to do things in a special moment"* (LL1).

In their research, Lima *et al.*¹⁹ show that one of the justifications given by the interviewee as to the non submission of the research to the CEP was the time factor: *there was no able time to submit the project to a CEP*. The anxiety about the deadline of the ethical assessment, also present in our study, can be related at some point to a possible ethical negligence from the non submission to the beginning of data collection without the ethics committee's authorization.

Such problem can be eased with the implantation of Platform Brazil, a new CEP-Conep system's resource created by CNS from the review of the National System of Information for Ethics Follow-Up in Researches Involving Human Beings (Sisnep), allowing to follow researches in its different stages. The system allows the presentation of digital documents, granting society access to public records from all approved researches. It is also possible to all involved to have access to the information in its totality, significantly diminishing the process time for projects in all CEP/Conep system²⁴.

In the conducted interviews certain mistakes regarding the need for CEP's assessment in researches involving human beings were noted: *"I have a project from (name of promoting organ) that did not required a pass through CEP (...) the organ investing in the research did not set this as a requirement, the research was conducted, published (...) that is, what I'm saying is that this is still not a general requirement"* (PE3); *"Today is more frequent for magazines to ask for it, which makes researchers have to pass their projects through CEP"* (PE3).

The lack of knowledge as to the need or even ignoring the requirement of the submission of researches involving human beings to CEP is extremely preoccupying to the scientific research. Lima *et al.*¹⁹ state that when the researchers of their study were asked about this, 65.5% said there was no such need; 18.0% didn't know of such requirement, and 16,4% justified the non submission with phrases such as *"it is not hospital policy"*; *"they were patients from my private practice"*; *"I was aware I needed to submit it, but didn't"*.

• **Non favorable consolidated opinion**

The assessment of the research protocol is made through the emission of a consolidated opinion, derived from a discussion and deliberation of CEP, with five possibilities: 1) approved, when there is no reservations to the protocol's content; 2) pending, when a specific review is recommended or a alteration of relevant information is requires; 3) removed, when after the deadline, the protocol remains pending; 4) rejected, when the protocol is not consistent with what is expected of an ethical proposal; 5) approved and forwarded to Conep/MS, in cases which require analysis at that instance¹⁸.

The interviewee's reaction to a non-favorable consolidated opinion on the research protocol caught our attention. The discontent in front of the rejection extended the rejection to the CEP: *"I respect it because we are in no place to judge nobody, I respect their point of view, but I will never submit it again"* (LL2); *"I had projects that were returned with this sort of notes, which I don't think it is CEP's responsibility, and it made me really uncomfortable, so much that I searched new types of researches that didn't require the committees approval"* (PE3).

The rejection speeches regarding a non-favorable decision show the frail knowledge of how the opinion is formed, using expressions such as *"point of view"* or questioning the real competence of such committee at that assessment. The consolidated opinion is a result of the comparison, mix and convergence of the members and follows a discerning assessment script recommended by Conep²⁵. According to this recommendation, the main reasons for rejection of research protocols involve unacceptable risky situations for the subjects, such as the use of placebos in comparative studies of new drugs; not guaranteeing the best proved therapeutic; inappropriate methodology, which may invalidate the results; and burdens to the vulnerable population, among others²³.

In situations of pending opinions, all researchers that had such experience proved to be more receptive and heeded the suggestions: *"I changed it to meet the criteria established by the ethics committee"* (BA1); *"I had no rejected projects, ok? I had projects that were returned for adjustments, we made them, heeded CEP's suggestion and developed"* (PE3).

In such cases, the CEP recommends a specific review or requires alteration or relevant information, without need for a new submission, but the alterations must be submitted to the CEP within 60

days. In cases where the project is not presented again until the deadline, the protocol receives the “removed” opinion. In both cases, pending or removed, data collection cannot begin¹⁸.

The opinion represents CEP’s positioning towards the submitted proposal, as well as the issues that endorsed the discussion of the assessment process²⁰. Therefore, a detailed opinion has a relevant role in the educational CEP’s role, contributing to the continuous education of researcher and institution, as well as committee’s members¹⁸.

- **Conducted researches**

According to Resolution 196/96, all researches involving human beings must be submitted to CEP’s appreciation before data collection. However, researches are still conducted without previous approval, which is highly concerning. In such way, the interviewee diverged as to CEP’s role in such cases: “It deserves special attention, even accelerating the ethics committee to retroact (...) why, what lead to it?” (LL2); “I believe it can ask the ethics committee to review it so that it can publish the project. I think it can even receive an observation on it, but it shouldn’t be stopped from publishing” (LL1); “In reality, this is cheating the system, and it is more a researcher’s commitment to ethics than the committee’s” (PE4).

Researches conducted without CEP’s authorization make ethical infractions, being the first of them not following the legal process of submission to the committee. Even if the study did not violate physical or psychologically the participants, the lack of previous assessment prevents the institution and society to assure participants have means to maintain their rights, without compromising their autonomy.

Francisconi *et al.*²⁶ discovered in their study that authors of articles published in national congresses didn’t always submit their research to previous ethical assessment. Of the authors who had any assessment done, many did not submit it to a CEP, but medical ethics committees, scientific committees and even peers or the direction of the institution. Having a CEP in the institution does not seem to ease the submission, for only 38.5% of interviewees submitted their researches to the committee. It can be understood from this that the resistance to the CEP, as well as the unfamiliarity with its role, needs to be discussed in the institutions to insure the ethics in researches.

- **Observation of plagiarism in academic research**

All scientific proposals must be endorsed, justified and well founded so that the project is relevant and ethical. Using third parties works as a guide is fundamental to understand the theme, as well as discuss and compare data, value communication and exalting relevant scientific publishing²⁷. However, reproducing published works, followed by omission of source, observed in all education levels, is becoming more and more frequent with the use of the internet and the copy and paste resources in computers²⁹. In the speeches of the interviewees it is noticeable the strong rejection of such practices: “I believe plagiarism should be flagged” (LL2); “Plagiarism is the proof that people are not ethical, use it indiscriminately. I’m completely against, it has to be rejected” (PE3).

With that focus, the current circumstances of scientific communication, along with the easy access enhanced with the internet, presents itself as an invitation to plagiarism²⁸. Such practice can occur in three different forms: full plagiarism, in which there is a transcription of the full text without any source quotation; partial plagiarism, in which sentences or paragraphs are copied with quotes of different sources to make it difficult to identify; and the conceptual plagiarism, in which concepts and theories are incorporated to the text as being created by the author²⁹. There is also the self plagiarism, in which there is the reproduction of previously published works by the author. These forms of plagiarism are not mutually exclusive and can occur simultaneously in some works.

In this context, researchers view as to the role of the CEP in such circumstances highlighted the ethical rejection, as well as the need of a report: “Assess a plagiarized research protocol, and I even think one of the CEP’s attribution should be to forward such protocol to the Federal Police, which is responsible and can evaluate if there was plagiarism or not” (L3); “Maximum penalty in case of plagiarism; rejection, remove from the institution, open a law suit, whatever” (PE3).

Plagiarism is defined by Law Lei 9.610³⁰, but detecting it can be difficult at times. In case of detection, the punishment is defined in the Penal Code, in its Article 184, which establishes a sentence of 3 months to a year or fine³¹.

Although it is indisputable that plagiarism is a serious ethical issue, it is hard to argue that such attribution be incorporated into the committee’s role, since it already conducts all study and analysis of the institution’s research protocols voluntarily. In light of the growing need to consider and analyze such

aspects too, it should be debated if it is not necessary to have a greater institutional support for the search of plagiarism prior to CEP's assessment.

Final considerations

The study showed that professors understand the CEP, as well as its concept on ethics and research from previous experiences with the process of their projects. The understanding of subjects under CEP's role is directly connected to the lack of knowledge of Resolution CNS 196/96.

Despite the knowledge of bureaucratic process for submission, from previous experience, there were gaps in the understanding of several issues of the resolution: recognition of bioethics principialism principles; conduction of assessment; composition and attributions of CEP. The content required at TCLE is known to the faculty members, but this instrument is usually structured from adjustments to preexistent model, without consideration to the mentioned bioethical principles – which are not regarded in a consistent and safe manner.

The superficial awareness of the guiding instrument for the ethics assessment directly compromises the meanings of the interviewee/CEP relation, the role of the committee to the issues evaluated. The misunderstanding of the constitution of such committee and its role led to uncertainty and rejection of pending or non-favorable opinions. In this sense, it is brought forward the educational CEP's role in forming researchers, aiming to stimulate practical changes in the production of research protocols.

The awareness of CEP's role proved to be frail and gapped. According to faculty members, the

submission to the committee is important to assure the rights of participants, although they understand that such process is necessary to allow the future publishing of the data. Such understanding is concerning, since the main objective of the CEP is to follow the recommendations of Resolution 196/96, and not the adequacy of the research to the publishing requirements.

In view of these aspects, the study contributed to enlighten the academic community on the CEP's role in the assessment of research protocols, as well as stimulate a reflection on the pressing need to adjust the protocol for analysis of the ethical aspects in qualitative researches, especially those which produce knowledge, where the research is in a area of many possibilities, but should all be guided by ethics.

This way it is suggested the need to program educational actions regarding ethics in science at the university, so that the researches meet their scientific and social role in an ethical manner, with conscious and autonomous researchers, who understand the relevance of the ethical standard in any situation, without breaking the sequence of ethical analysis and preserving involved subjects.

It is also important to note that the study has limitations related to the impossibility to make generalizations, due to presenting knowledge gathered in a contextualized way, proposing the conduction of a multi centered study so that it is possible to compare data, searching other conclusions. It can be considered, however, that given the relatively uniform characteristics of the analysis process of project by the CEP and the state of the art knowledge on the theme by the different areas of knowledge, it is possible that the findings of this study will be found in other context as well, even if in different degrees of occurrence.

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Authors' participation in the article

The authors are equally responsible for the definition of the object of study, methodological approach, bibliographic research, creation and application of instrument, data analysis, writing and reviewing the article, and approval for publishing.

