

ETHICS IN RESEARCH: RESEARCH ETHICS COMMITTEES' EVALUATIONS AND PAPER PUBLICATIONS IN BRAZILIAN JOURNALS

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Abstract: Resolutions 466/2012 and 510/2016 from the Brazilian National Health Council present the determination that each institution which performs researches that involve human beings need to have a Research Ethics Committee (CEP). Those Committees have, as their first attribution, to evaluate research protocols for studies that involve human beings, analyzing ethical aspects of the work, and also to have a consultive and educative role in ethical matters. The ethical issues on research are becoming a debated topic, and so the CEP's evaluation becomes more critical as ethical validation of the research. This paper aims to analyse the role of CEP's ethical evaluation as a requirement for publication in Brazilian journals. The methodology consists in the analysis of "instructions to authors" from Brazilian Journals. The selection of journals will be made amongst the best classified in the Brazilian journal classification (QUALIS-Capes). Initial results suggest that, despite there are some journals that demand the CEP ethical analysis to publish the research, there is still a large number of journals that do not require a CEP approval to publish the paper, casting aside the importance of the evaluation.

Key words: instructions to authors, publication, studies.

1. Introduction

Brazil has its own model for regulating ethics in research – the CEP/CONEP model. In this model, which still has a significant influence from the biomedical sciences, there is a strict relation of the evaluation performed by the CEPs (Research Ethics Committees) and the risks and results of the research, as well as eventual conflicts of interests.

The CEPs are independent evaluators, which can approve or not a research protocol or project by assessing their risks to the research subjects and its impact as well as measures to minimize those risks.

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Since the model is not implemented by law – it is in administrative regulations – it cannot be imposed as an obligation to the researchers. As such, the academic journals have a critical role to play in the model: using the CEP approval as a requisite for paper publication, they are, in fact, implementing the mandatory aspect of the CEP approval for any research that has the intent of being published.

This paper aims to analyze the adoption by highly classified Brazilian journals of the CEP approval as a requirement for publication. In order to do so, a sample of A1 journals published in Brazil was selected, and for each of them, their websites were checked for that requirement.

This paper is divided into 7 parts. After this brief introduction, it exposes the origins of norms for research ethics, and particularly the Brazilian CEP/CONEP model as well as the importance of their approval of the research. After the presentation of the methodology used in this research, the paper presents the results. In the end, some final remarks.

2. Norms for scientific ethics

Brazil follows some international norms, taking them as a basis for internal normative production. The importance of standards such as the Nuremberg Code and the Helsinki Declaration cannot be underestimated and is the basis for the creation of the Resolutions that will be mentioned in this paper.

At the end of the trials of Nazi physicians for experiments with human beings in 1947, the trial judges and doctors developed the principles inscribed in the Nuremberg Code. As a significant contribution to the development of ethics in human research, while objectively analyzed, the importance of the informed consent of the research participant (Annas; Grodin, 2018; Marques Filho, 2007) was defined. Despite criticisms of the possibility of plagiarism of the Nuremberg Code concerning existing standards in Germany in 1931 (Ghooi, 2011), there is no doubt about its importance as a framework for relations between researcher and research subject.

The successor to such a norm is the Declaration of Helsinki, dated 1964, which seeks to guide the work of medical research concerning the involvement of human beings, and the importance of using ethical criteria to guarantee the fundamental rights of human beings submitted to medical experiments (WMA, 1964). Since then, the Helsinki Declaration has undergone several changes, the last one being dated from 2008. There are also criticisms of the norm, such as those made by Allebeck (2002), but its treatment as the basis for the creation of research ethics is consolidated.

Based on these documents, a movement for the analysis of research ethics is beginning to emerge throughout the world, as a rule, to enable scientific research and publication of works involving human beings as subjects of academic work (Batista and Andrade; Bezerra, 2012).

In Brazil, research regulations involving human beings only began to emerge after more than 20 years of the first version of the Declaration of Helsinki - and a few years

after its third version, 1983 - in July 1988, with the publication of the National Health Council Resolution Number 1/1988. It is noteworthy that this occurs a few months after the promulgation of the Constitution of the Federative Republic of Brazil of 1988. Such Resolution defines the risk to the respondents as well as some basic rules of research with human beings - the need for informed consent, for example. (CNS, 1988).

Besides, Resolution 1/1988 determined the existence of Research Ethics Committees at any health institutions conducting research with humans. The normative anomie of such Resolution results in allegations of abuse by researchers against the integrity of women during contraceptive research (Hardy et al., 2004). There were few contributions that this norm brought in terms of ethics in research (Barbosa et al., 2011).

The need for changes in the research ethics analysis model in Brazil led to changes in Resolution 1/1988, resulting in Resolution 196 of 1996:

Seven years later, in 1995, there was a need for the Resolution to be revised. To this end, an Executive Working Group (GET) was formed, which made a prior consultation to the scientific community on the internet and accepted several suggestions for enriching the document, a process that resulted in the elaboration of Resolution 196/96. Although recent - instituted in 1996 - this Resolution has shown increasing importance for the development of human research in the country, especially for instituting a system of evaluation of research projects with national articulation, consolidated by the creation of research ethics committees (CEP)(BARBOSA *et al.*, 2011, p.524-525).

A central body forms the system of analysis of research ethics in Brazil, the CONEP - National Commission for Research Ethics, and by existing organs in the institutions where researches are carried out with human beings the CEP - Research Ethics Committees. According to the Resolution itself, they are standards that regulate research with human beings and are based "on the main international documents that emanated declarations and guidelines on research involving human beings" (CNS, 1996, Preamble). The purpose of this system is to analyze and issue opinions on research projects to be carried out in Brazilian institutions.

In December 2012, another resolution was approved by the National Health Council, number 466/2012, whose objective is also to regulate research with human beings in Brazil. However, this Resolution broadly defines research, determining the use of the scientific method (Guerriero, Minayo, 2013)

Lastly, Resolution 510/2016, from the same body, arises from the requirement of research in the human and social sciences to "respect and guarantee the full exercise of the rights of the participants and must be designed, evaluated and avoid possible harm to the participants "(CNS, 2016, Preamble).

3. Resolutions 466 and 510 of the National Health Council

The relationship between research ethics and health sciences is clear. Due to the seriousness of possible aggressions to life and health of the subjects of the research, and the relative lesser aggressiveness of researches in human and social sciences that seek data in human beings, the biomedical area always had a fundamental role in the formulation of norms about ethics in search.

In Brazil, such a relationship could not be more evident. Despite the nonexistence of laws that deal with this issue, the Resolutions produced after the 1988 Constitution were created by the National Health Council.

Since there is no law that defines as necessary the approval of the research by Ethics Committees, the request for a pronouncement by the CEP-CONEP system is traditionally carried out by the biomedical areas. However, the humanities and social sciences refer to it when they consider it is necessary.

However, the approval of research in the areas of humanities and social sciences has obstacles that are strictly related to the vision of science adopted by the Resolutions issued by the National Health Council. The main criticism of the relationship between ethics in research and health, especially in Brazil with Resolutions 196 and 466,

Is to consider that the relation of the researcher with the participants of the research is established and maintained in the same way in the different scientific communities. In the case of the social and human sciences, in general, the participants are not only seen as objects of study but interact with the researchers and their collaboration has a character of interpretation of the first order [...]. That is, the researchers and their interlocutors are active actors in the research process since, in general, the knowledge of the social and human sciences is generated in intersubjectivity. Also, the researcher usually enters the usual context of the participants and the ethnographers, for example, live in the communities they study. This intense coexistence between the research team and participants generates a kind of knowledge that does not occur a priori, and can not, therefore, be predicted in a research protocol (Guerriero and Minayo, 2013).

The various inadequacies of Resolutions 196 and 466 for ethical analysis of research in the human and social sciences are exposed by Guerriero and Bosi (2015), demonstrating a "biomedical hegemony" and a positivist view that disqualifies the subject's knowledge. Like this,

One of the most plausible questions is that CEP-CONEP members themselves encounter difficulties in reviewing social surveys, because not always the terms of Resolution No. 196/96 and now of Res. 466/12

are immediately applicable to the analysis of situations. This problem has caused delays or non-approval of social projects, even when there are no ethical inadequacies (Guerriero and Minayo, 2013).

4. The Qualis/CAPES journal evaluation

In Brazil, the evaluation of journals is done by a governmental organ called CAPES – Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (Coordination for improvement of Higher Level Personnel). To do so it was created a web system which encompasses the evaluated journals and their respective grades. It is the Qualis (qualis.capes.gov.br).

The Qualis classification, from top to bottom, is A1, A2, B1, B2, B3, B4, B5 and C. The higher the journal is classified, the better the classification and more points a paper published in it receives, in order to analyse the researcher's production.

The classification is verified for each of the knowledge areas defined by CAPES, and is based on a number of characteristics of the journal, such as having an editorial committee; regularity; institutional diversity of authors, indexed by ISI, Scopus or Scielo; and so forth. The criteria are different for the diversity of knowledge areas defined by CAPES. There is some criticism on the evaluation mechanisms used by CAPES (for instance, in Oliveira et al., 2015 and Silva, 2009).

As such, it was expected that journals which are better qualified would keep a strict code of ethics over the papers they publish. The researches that are described in the papers should be verified for any ethical issue before the editors accept to publish the paper.

5. Research Ethics Committee and its approval

Since there is no law determining the referral of research to the Research Ethics Committee, the need for its approval is indirectly implemented. Thus, some scientific journals present, as a requirement for publication, the approval of the research by a CEP:

Local scientific societies and journals often alert the researcher to the need to submit work to the CEP, but sometimes compliance monitoring is neglected. An example of this are the cases of abstracts that are presented at scientific meetings in categories known as free themes, in which there is no obligation of proof of appreciation by a CEP. Publishers and scientific organizations should address this problem by requiring adherence to the national and international ethical standards of studies that authors submit for evaluation and publication, whether in periodicals or scientific events (Sá and Lima, 2010, page III)

In 1999, Sardenberg *et al.*, analyzing Brazilian journals, stated that "the editorial policy of scientific journals, aiming to improve not only the technical aspects of the articles but also the ethics of the studies, could contribute in an effective way to the overall improvement of Brazilian publications medicine, biomedicine, dentistry, nursing and the general sciences"(Sardenberg *et al.*, 1999, p 301). This improvement brought by the author would arise from the determination and collection, on the part of the periodicals, of the previous analysis by an ethics committee.

In health, this analysis is already something more consolidated. According to Sardenberg *et al.* (1999),

There has been a definite change in focus, since there is no longer any debate about the publication or not of articles that are clearly and generally considered unethical, but whether scientific journals should publish a research that has not included, in their implementation, informed consent or has not been analyzed and approved by institutional ethics committees (p. 296).

5. Methodology

The present research is exploratory, qualitative research that analyses the ethical criteria demanded by higher periodicals to publish humanities and social sciences research papers, especially the importance of the Research Ethics Committee approval of the research.

All the CAPES' knowledge areas were used in this research, except for Zootechnics, Materials, Math/Statistics, Geosciences, Engineering and Computation, since they have a less probable data collecting that affects human beings.

Among the CAPES journals, removing the above areas, a random sample of 813 journals classified as A1 were selected. Amongst those, just Brazilian journals were included in the research, since the regulation of CEPs is Brazilian. Eighty journals matched those criteria, amongst the 813 randomly chosen.

In Qualis/CAPES, a journal can be classified in more than one area. As such, one area was selected for each paper at random, so that they would not be chosen more than once. The 80 journals selected were classified in 19 main areas. From those, 3 journals had their website offline. They were excluded as well, leaving a total of 77 journals to be analysed.

For each of the journals, the "Instructions to authors" section of their website was accessed (or others that pointed the requisites for publication), and it was checked if that journal demanded the CEP's approval, or if there was any ethical issue observance whatsoever.

The journals were, then, classified as not having demands on research ethics; presents considerations on research ethics, but CEP approval is not required; and CEP approval required.

6. Results

The determination from a journal to demand the CEP approval for research in order to publish it is a significant mechanism of implementation of the CEP/CONEP system and imposing minimum ethical standards in research. It is the main criteria for guaranteeing the ethical parameters in the risks that human subjects are exposed to in researches.

First of all, it is essential to be said that almost every journal demanded some research ethics levels for the papers, such as originality, the combat on plagiarism and the adequate citation and reference markings. The main focus in this research is the journals' view on the researcher-subject relation, and the codes of ethics that should be followed to minimize any problems that can occur for the subjects, as well as conflicts of interests.

50,65% of the journals analysed have some kind of norms on research ethics. Those vary from a journal to another but always imposing some form of obligation to the researcher.

But only 23,38% of the journals analysed demanded the approval of a CEP when the research dealt with humans as subjects. As aforementioned, this would be very important to implement the very core of Brazilian ethics research control, the CEP/CONEP model.

Without the massive adoption by different journals of the requisite of CEP approval, researches that consider the CEP to be time-consuming, slow and challenging to manage, as well as researches that disregard ethical procedures, such as the informed consent will still have a variety of journals to choose for publishing.

On the other hand, 27,27% of the journals presented norms on research ethics, but other than the need for CEP approval. In general, those journals demanded some form of declaration from the researcher that ethical standards were met in the research – but that declaration is requested after the research – and not before, as in the CEP model. Thus, it cannot guarantee the real adoption of ethical values in the research.

The journals that presented those norms usually adopted the guidelines from COPE – Committee on Publication Ethics (<https://publicationethics.org>). Despite the importance of the institution and its guidelines and policies, adoption of those norms cannot improve the Brazilian ethics review model, since it does not impose the necessity of the intervention of a CEP in order to publish the paper. In other words, the CEP becomes irrelevant to researches that will be published in that journal.

It is essential to observe that almost 50% of the sample journals did not have any consideration about subject ethics in research. The results of the lack of ethical norms by those journals are massive in the ethical review model in Brazil. Since there is no need for CEP approval (neither for a simple declaration), the researcher is free to perform as it pleases him, and maybe willingly, maybe unwillingly, commit some sort of unethical procedure expose the subject to a risk that otherwise could be avoided.

The data collected exposes that the effective contributions Brazilian journals could have in the improvement of both research and resulting publications, as mentioned by Sardenberg et al. (1999).

In adopting the Brazilian research ethics model, the journals would be limiting the possibility of unethical behaviour from the researcher. As Sá and Lima (2010) pointed, the implementation of the CEP/CONEP model demands the publishers to appropriate the model, and address the CEP approval in a mandatory manner.

7. Conclusions

This study aimed to analyse the relationship between the Brazilian research ethics model, based in the CEP/Conep system, and the publishers of academic journals in Brazil. This was made specially by the imposition made by journals that publications would only be made if the research had a CEP validation.

That imposition would secure the need of submitting the research to a CEP since the approval can only be achieved after the analysis of the research by a CEP – and it is done before the field research begins. It could also consolidate the importance of the CEP/CONEP model as an institution of utmost importance in research, as well as improve researches and papers since they have to be assessed by those organs.

The research analysed randomly 77 journals form the top classification (A1) of the Qualis/CAPES. Those journals usually have guidelines on plagiarism, originality and citation and references, but in almost 50%, have no regulations on ethical parameters between researcher-subject or conflicts of interests. Thirty-nine Journals have some kind of guidelines regarding those aspects of ethical responsibility, but only 18 demand the submission of the research to a CEP and its approval to publish the paper.

It is a paradox that the same government that implements rules regarding research ethics by one of its organs (National Health Council) have it in no regard when assessing and evaluating the journals (by CAPES). Even journals highly classified in the Qualis/CAPES have no regard for the CEPs.

The publishers also have major roles in the implementation of the CEP/CONEP, which are being cast aside, since the approval is not a requirement for paper publication. It is a disservice to the Brazilian science and to the ethical model Brazil aims to implement.

This paper is limited by the sample it has utilized. In order to assess the real influence of CEP approval in publication, it demands to analyse the entire group of Qualis/CAPES classified journals – which is a massive effort.

Future researches in the area may analyse all the Qualis/CAPES journals, or maybe the A class ones, in order to check the importance of CEP approval not only for journals but also for the CAPES itself. Researches can also assess the role of Brazilian Post-Graduate Programs in implementing the CEP/CONEP model by requiring from students approval in order to begin the field researches.

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